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Contents

Review Articles

- Trachyspermum ammi* (L.) *In Vitro* Analyses on Pharmacognostical, Physicochemical, Phytochemical, and Antioxidant Aspects in Unani Medicine**
Ayman Kirmani, Rasikh Javaid Nengroo, M. Aslam, Abdul Wahab, Aisha Siddiqui 1
- General Dietary Principles in Unani Medicine: Aligning Evidence-based Nutritional Science with Traditional Wisdom**
Noman Anwar, Zaheer Ahmed, Najmus Sehar, Farooqui Shazia Parveen, Athar Parvez Ansari, Shaheen Akhlaq 6
- Unani Perspective of PCOS with Special Reference to the Potential Benefits of *Satāwar* (*Asparagus racemosus* Willd.) for Women's Reproductive Health**
Deeba Anwar Khan, Azhar Jabin, Shazia Jilani, Roohi Azam, Saman Anees 13
- Sū'-i-Mizāj Jigar Hārr*: A Comprehensive Exploration of Its Conceptual Framework, Systemic Manifestations, and Management in Unani Medicine**
Tabish Bashir, Tariq Nadeem Khan, Abid Ali Ansari, Aqsa Shafi 23

Original Articles

- Physicochemical Standardization of *Maghz-e-Pambadana* (Kernel of *Gossypium herbaceum* L.)**
Asrar Ahmed, Mohd Aftab Ahmad, Mohd Akhtar, Mohd Asif, Uzma Bano 31
- Evaluation of Unani Decoctions in *Hazāz* (Pityriasis capitis) – A Randomized Comparative Clinical Trial**
Sheema, Mohd. Aleemuddin Quamri 36
- Evaluating the Effectiveness of *Saussurea Lappa* Oil (Rogane Qust) in Carpal Tunnel Syndrome: An Open-label Clinical Trial**
Mohamed Rasheed Fathima Raziya, Mohd Aleemuddin Quamri, Farooqui Shazia Parveen, Md Anzar Alam 41
- Evaluation of Acute Toxicity and Immunomodulatory Activity of a Polyherbomineral Formulation *Qurs Haiza* in Wistar Rats**
Bazilah Majeed Reshi, Athar Pervez Ansari, Mohd Musaib Bhat, Pankaj Goswami, Ifra Qayoom, Pawan Kumar, Ram Pratap Meena 47

Case Reports

- Efficacy of *Dimād-i-Safūf-e-Waj* in Segmental Vitiligo**
Mohd Shahid, Iram Naaz, Arshad Jamal 54
- Therapeutic Efficacy of an Unani Traditional Regimen in Chronic Non-healing Ulcer**
Athar Parvez Ansari, Farooqui Shazia Parveen, Muhammed Ibrahim, Noman Anwar 58

Trachyspermum ammi (L.) *In Vitro* Analyses on Pharmacognostical, Physicochemical, Phytochemical, and Antioxidant Aspects in Unani Medicine

Abstract

Background: *Trachyspermum ammi* (L.) Sprague ex Turrill (*Ajwā'in*) is a widely known medicinal herb used in the traditional systems of medicine for treating gastrointestinal, skin, respiratory, and liver disorders. **Objective:** This study aimed to evaluate the pharmacognostical, physicochemical, phytochemical, and antioxidant properties of *T. ammi* seeds to provide a scientific basis for their traditional use. **Materials and Methods:** Physicochemical parameters, including total ash, water-soluble ash, acid-insoluble ash, moisture content, and pH, were assessed. Phytochemical screening was performed in aqueous and hydroalcoholic extracts. Antioxidant activity was evaluated using 2,2-diphenyl-1-picrylhydrazyl (DPPH) assay, and total phenolic content (TPC) was determined by the Folin–Ciocalteu method. **Results:** Physicochemical analysis confirmed purity within standard limits ([total ash 10.6%, water-soluble ash 11.2%, acid-insoluble ash 0.76%, moisture 9.5%, total oil 4%]. pH values were 3.20 [1% solution] and 3.35 [10% solution]). pH values were 7.28 (1% solution) and 6.14 (10% solution). DPPH assay showed potent antioxidant activity (IC₅₀ 48.44 µg/mL). TPC was 21.52 ± 0.52 µg/mL in aqueous extract and 14.47 ± 0.58 µg/mL in hydroalcoholic extract. **Conclusion:** *T. ammi* exhibits quality, purity, and significant antioxidant potential, validating its role in Unani medicine as a natural therapeutic agent.

Keywords: *Ajwā'in*, antioxidant activity, fluorescence analysis, phenolic content, physicochemical analysis, phytochemical, *Trachyspermum ammi* (L.) Sprague ex turrill

Introduction

Nature has always been regarded as the most valuable resource for the evolution and sustenance of life on the earth.^[1] Since prehistoric times, plants have served as a primary source of medicine in traditional healthcare systems.^[2] Among these, the *Unani* system of medicine – an integral part of the Ayurveda, Yoga, Unani, Siddha, and Homeopathy framework – is widely recognized for its reliance on natural remedies.^[3] Rooted in ancient Greek concepts and enriched by Persian, Arab, and Indian contributions, *Unani* medicine emphasizes balance of bodily humors (*Akhlat*) for health and well-being.^[4]

In *Unani* practice, drugs are classified according to their origin (*Māhiyat*) into plant, mineral, and animal sources.^[5] Plant-based remedies remain, especially important due to their accessibility, safety, and cost-effectiveness.^[6] One such drug is *Trachyspermum ammi* (L.) Sprague ex Turrill (*Ajwā'in*), family Apiaceae, which

has been used both as a spice and therapeutic agent.^[7] Its seeds are well known for carminative, digestive, antispasmodic, and antimicrobial actions.^[8] Chemically, *Ajwā'in* contains volatile oil rich in thymol, p-cymene, γ-terpinene, α- and β-pinene, along with minerals and secondary metabolites such as flavonoids, alkaloids, tannins, glycosides, and saponins.^[9]

According to *Unani* principles, *Ajwā'in* has a “hot” and “dry” temperament (*Mizāj*) and is prescribed in conditions such as gastrointestinal disorders (*Amrāḍ-i-Medi*), skin disorders (*Amrāḍ-i-Jild*), hepatic ailments (*Amrāḍ-i-Kabid*), respiratory complaints (*Amrāḍ-i-Dard-e-Seenā*), and renal disorders (*Amrāḍ-i-Gurdah*).^[10] Pharmacognostical studies are essential for authentication and quality control of crude drugs, while modern analytical tools enable validation of traditional claims.^[11]

Rationale

Despite extensive traditional use, there is a lack of integrated studies that combine

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pharmacognostical, physicochemical, phytochemical, and antioxidant investigations of *T. ammi*. Such work is essential to establish scientific validation and ensure quality assurance in *Unani* formulations.

Objectives

This study was undertaken to (i) evaluate the pharmacognostical features of *T. ammi* seeds, (ii) determine their physicochemical parameters, (iii) conduct phytochemical screening, (iv) assess antioxidant activity through *in vitro* assays, and (v) correlate findings with *Unani* claims.

Materials and Methods

Plant Material Collection and Authentication: *T. ammi* seeds were purchased from Khari Baoli market, Old Delhi, and authenticated at NISCAIR (Ref No-NIScPR/RHMD/Consult/2023/4317-18). The seeds were washed, cleaned, shade dried, and powdered.

Preparation of powder

Seeds were collected and made into coarse powder using an electrical grinder and stored in an air tight glass container.

Preparation of Extracts: 100 g of seed powder was extracted in Soxhlet with distilled water (yield 23% w/w). Hydroalcoholic extract (50:50 ethanol-water) gave 14% yield. Powder was subjected to physicochemical analysis as per the World Health Organization and Indian Pharmacopoeia guidelines.^[6-8]

Physicochemical Analysis: Ash values (total, water-soluble, and acid-insoluble), moisture content, and pH were determined. Oil content was estimated using a Clevenger apparatus. Fluorescence analysis was performed under daylight and UV (254/366 nm).

Determination of ash value

Total ash

The 2.0 g of powdered dried root was incinerated in a silica crucible at 450°C in a muffle furnace until white

(carbon-free). The crucible was cooled in a desiccator and weighed to determine the total ash content. The content of total ash in the dried material was calculated as^[2]

$$\% \text{ Total Ash value} = \frac{\text{Weight of total ash}}{\text{Weight of drug taken}} \times 100$$

Acid insoluble ash

$$\% \text{ Acid insoluble ash} = \frac{\text{Acid Insoluble Ash Weight}}{\text{Weight of Sample}} \times 100$$

Water-soluble ash

$$\% \text{ Water soluble ash value} = \frac{(\text{Weight of total ash} - \text{Weight of water insoluble ash})}{\text{Weight of drug taken}} \times 100$$

Determination of Moisture Content of *Trachyspermum ammi*

A quantity of 5 g of powdered drug sample was taken in a tarred evaporating dish to dry it at 105°C for 6 h.

% Moisture Content =

$$\frac{\text{Weight of the sample after drying at } 105^{\circ}\text{C}}{\text{Weight of drug taken}} \times 100$$

Determination of pH value of *trachyspermum ammi*

pH at 1% – In 100 mL of distilled water, 1 g of drug was dissolved and then filtered. Later on pH of drug solution was checked, by immersing standard glass electrode into the filtrate. pH at 10% – In 100 mL of distilled water, 10 g of drug was dissolved and then filtered. Later on, pH of drug solution was checked, by immersing standard glass electrode into the filtrate.^[2]

Total oil estimation by clevenger apparatus

100 g of *Ajwā'in* was combined with 500 ml of distilled water in a Clevenger apparatus and processed for 6 h. A total of 4 ml of *Ajwā'in* oil was

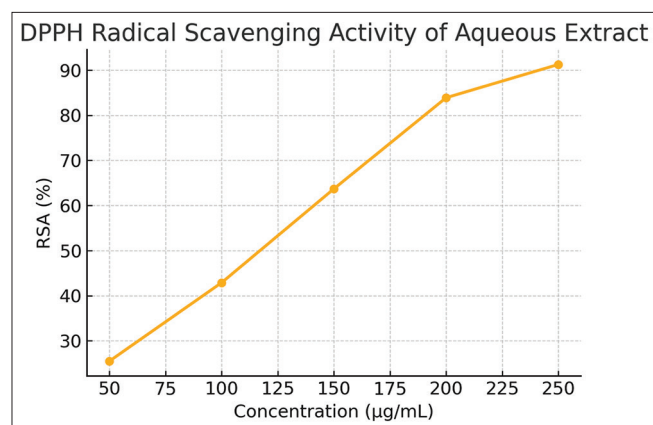


Figure 1: 2,2-diphenyl-1-picrylhydrazyl radical scavenging activity of aqueous extract. DPPH: 2,2-diphenyl-1-picrylhydrazyl

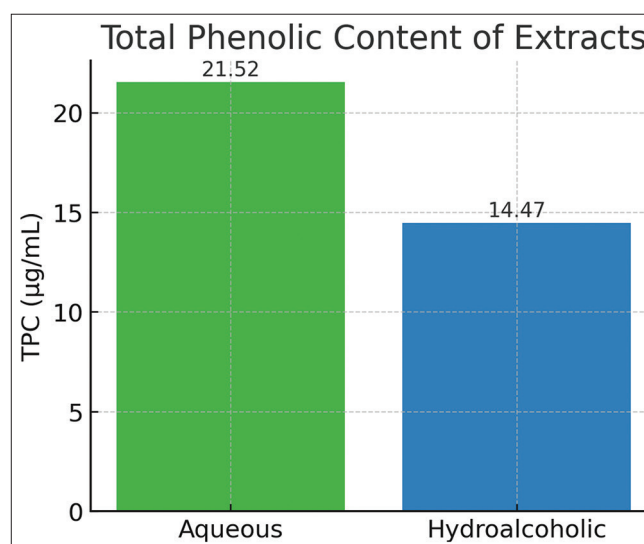


Figure 2: Total phenolic content of extracts. TPC: Total phenolic content

extracted, and the yield was calculated using the appropriate formula.^[2]

$$\% \text{ Oil Content (v / w)} = \frac{\text{Volume of oil Extracted (ml)}}{\text{Weight of Sample Taken}} \times 100$$

Fluorescence analysis

Certain herbs exhibit fluorescence when exposed to UV light on their cut surfaces or powder. Fluorescence examination was performed on the root powder under both daylight and UV light (254 and 366 nm)^[9]

Phytochemical analysis

Aqueous and hydroalcoholic extracts were tested for alkaloids, carbohydrates, flavonoids, glycosides, steroids, tannins, organic/phenolic acids, and amino acids using standard reagents.^[12]

Table 1: Physicochemical parameters of *Trachyspermum ammi* (L.) Sprague ex Turrill

Parameter	Result
Total ash	10.6%
Water-soluble ash	11.2%
Acid-insoluble ash	0.76%
Moisture content	9.5%
pH (1% solution)	3.20
pH (10% solution)	3.53
Total oil	4%

In vitro antioxidant study

Using the stable radical 2,2-diphenyl-1-picrylhydrazyl (DPPH) technique, the antioxidant activity was assessed. The DPPH solution was prepared by dissolving 30.0 mL of methanol to the DPPH (10 mg of molecular weight 394.32 g/mol) then diluting the mixture to a final volume, ensuring a homogenous solution, resulting in a DPPH concentration of 0.5 mM (equivalent to 200 µg/mL).

Calculation of free radical scavenging activity

$$\% \text{ of Inhibition} = \frac{[\text{Abs. (control)} - \text{Abs. (sample)}]}{\text{Abs. (control)}} \times 100$$

Where, Abs. control is the absorbance of DPPH radical + methanol; Abs. sample is the absorbance of DPPH radical + extract/standard.

Total phenolic content

Total phenolic content (TPC) was determined using Folin-Ciocalteu reagent with gallic acid as standard.

Results

Physical-chemical parameters such total ash, water-soluble ash, acid-insoluble ash, moisture content, pH, and total oil were measured in this study [Table 1]. Simply put, the ash value indicates the inorganic substances that naturally exist in crude drugs as well as different contaminants as silicate, carbonate, and oxalate. Three

Table 2: Fluorescence analysis of *Trachyspermum ammi* (L.) Sprague ex Turrill

Treatment of powder with different chemical reagents	Short UV light (254 nm)	Long UV light (366 nm)	Visible light
Powder alone	Green	Fluorescent yellow	Light brown
Powder + 50% H ₂ SO ₄	Yellow	Light green	Brown
Powder + Glacial acetic acid	Green	Dark yellow	Yellow
Powder + concentrated H ₂ SO ₄	Dark green	Lawn green	Orange brown
Powder + 5% KOH	Revolution green	No fluorescence	Marigold yellow
Powder + 10% NaOH	Forest green	Black	Marigold yellow
Powder + 10% NaOH + concentrated HNO ₃	Pastel green	Black	Bumble bee yellow
Powder + Mayers reagent	Dark green	Brown	Yellow
Powder + Dragendorff's reagent	Forest green	No fluorescence	Orange
Powder + Hager's reagent	Kelley green	No fluorescence	Bumble bee yellow
Powder + Benedict's reagent	Emerald green	Black	Forest green
Powder + Fehling's solution	Green	No fluorescence	Olive green

UV: Ultraviolet

Table 3: Phytochemical analysis of *Trachyspermum ammi* (L.) Sprague ex Turrill in aqueous and hydroalcoholic extracts

Phytochemicals/tests	Aqueous extract	Hydroalcoholic extract
Alkaloids (Dragendorff's test, Hager's test)	+	+
Carbohydrates (Anthrone test, Benedict's test)	+	+
Flavonoids (Shinoda test, Ferric chloride test)	+	+
Glycosides (Borntrager's test – Anthraquinone glycosides)	+	+
Steroids (Liebermann–Burchard's test)	+	+
Tannins (Lead acetate test, Ferric chloride test)	+	+
Inorganic acids (Sulphate test, Carbonate test)	+	+
Organic acids (Malic acid test, Oxalic acid test)	+	+

Table 4: Total phenolic content of extracts

Extracts	Concentration (µg/mL)	Mean±SD
Aqueous extract	100	21.52±0.52
Hydroalcoholic extract	100	14.47±0.58

SD: Standard deviation

Table 5: 2,2- Diphenyl-1-picrylhydrazyl radical scavenging activity of aqueous extract

Concentration (µg/mL)	RSA (%)
50	25.50
100	42.9
150	63.7
200	83.9
250	91.27
IC50	48.44 (µg/ml)

RSA: Radical-scavenging activity, IC50: Half-maximal inhibitory concentration

Table 6: Absorbance of standard compound (Gallic acid)

Concentration (µg/mL)	Absorbance (mean) λmax=716 nm
0.5	0.11
1	0.15
2.5	0.20
5	0.20
10	0.28

distinct methods—total ash, water-soluble ash, and acid-insoluble ash—were used to calculate the ash value. The total amount of material left over after ignition is measured using the total ash. A component of total ash, acid insoluble ash indicates the concentration of silica. The water-soluble component of total ash^[13] is known as water-soluble ash. According to the results of our study, the total ash content of *Trachyspermum ammi* seeds was 7.6%, whereas the water-soluble and acid-insoluble ash values were 19.2% and 0.76%, respectively. There should be no harmful foreign material present at all in the plant material. *T. ammi* was discovered to have a minimal amount of foreign materials, confirming their quality. The increased water content in medicinal plants promotes the growth of different microorganisms, insects, or fungi, which in turn causes degradation and hydrolysis.^[14] We observed that the moisture content in our study was 4.5% which was within permissible limits. Determining the pH value at various concentrations provides insight into the existence of basic and acidic botanical constituents in plant materials.^[14] The 1% and 10% solutions have corresponding pH values of 7.28 and 6.14. It was found that there was 4% total oil content. The primary component that gives ajwain seeds their distinctive flavor is the volatile oil found in them. The physicochemical parameters of *Trachyspermum ammi* seeds showed in Table 2 that the material is within acceptable limits for purity and quality.

Fluorescence analysis

The phenomenon known as fluorescence is displayed by different chemical components found in plant material when exposed to ultraviolet light. This is one way to describe the basic substance. Under UV light, the crude medication displayed varying fluorescence at various wavelengths. The drug's various phytochemical ingredients are the cause of this. In alkaline applications flavones that are pale yellow in aqueous conditions turn bright yellow when exposed to UV radiation. When 50% H2SO4 is applied to phytosterols, they glow green when exposed to UV light. In an alkaline state, coumaric acid appears yellowish green when exposed to UV light. When exposed to brief UV radiation, terpenoids glow yellow-green. Berberin exhibited a little yellow glow.^[15] The fluorescence study revealed that *Trachyspermum ammi* seeds exhibit distinct color patterns when treated with various reagents and observed under visible and UV light shown in Table 3.

Discussion

Physicochemical parameters confirmed the purity and quality of *T. ammi* seeds [Table 1]. Moisture content (4.5%) was within the safe limits. pH was 7.28 (1%) and 6.14 (10%). Total oil content was 4%. Fluorescence analysis [Table 2] showed distinct patterns confirming characteristic constituents. Phytochemical screening [Table 3] demonstrated the presence of alkaloids, flavonoids, glycosides, tannins, phenolics [Table 4], steroids, and organic acids, confirming medicinal value. Antioxidant activity was strong, with IC50 = 48.44 µg/mL [Table 5 and Figure 1], comparable to standard antioxidants. TPC was higher in aqueous extract (21.52 ± 0.52 µg/mL) compared to hydroalcoholic extract (14.47 ± 0.58 µg/mL) [Table 6 and Figure 2]. This correlates with better antioxidant potential in aqueous extract. These findings validate traditional claims of *Ajwā'in* in Unani medicine and highlight its role as a natural antioxidant.

Conclusion

Pharmacognostical, physicochemical, phytochemical, and antioxidant analyses of *T. ammi* seeds confirm their quality, purity, and therapeutic potential. The characteristic ash values, oil content, fluorescence behavior, phytochemical profile, and antioxidant capacity establish a strong basis for their continued medicinal use in Unani medicine. Data support the role of *Ajwā'in* as a safe, natural antioxidant, and further studies may isolate active compounds for new therapeutic leads.

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Conflicts of interest

There are no conflicts of interest.

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General Dietary Principles in Unani Medicine: Aligning Evidence-based Nutritional Science with Traditional Wisdom

Abstract

Food and drinks exert profound effects on both physical and mental well-being and play a central role in preserving human health. Although modern nutritional science focuses on biochemical components such as macro- and micronutrients, the Unani medical system integrates a holistic framework that features individualized and dynamic dietary regulation. Firmly grounded in the doctrine of *Mizāj* (temperament), *Akhlat Arba'a* (four humors), and *Asbāb Sitta Darūriyya* (six essential factors), Unani dietetics considers not only what to consume, but also when, how, and under what conditions food should be consumed. Acknowledging the concept of *Ilāj bil Taghdhiya* (dietotherapy), Unani scholars such as Rāzī, Ibn Sīna, and Rabban Tabarī considered food as both the source of nourishment and the medicine, a central pillar to health preservation and disease prevention. This review explores general dietary guidelines enumerated in Unani classical texts and correlates them with scientific evidence from contemporary nutritional science. Through an extensive review and analysis of classical Unani texts and modern literature, key dietary dimensions are identified, which include meal timing and quantity, food quality, emotional state during eating, food selection based on temperament and season, fluid intake, and postmeal practices. The findings revealed striking coherence between Unani principles and modern concepts such as chrononutrition, personalized nutrition, and mindful eating. These convergences indicate the enduring scientific relevance of traditional dietary wisdom and its potential integration into modern preventive and therapeutic nutrition strategies.

Keywords: Fluid intake, meal timing, mindful eating, personalized nutrition, postmeal practice, Unani dietary principles

Introduction

Diet, serving as the primary source of essential nutrients, plays a crucial role in human health.^[1] Although contemporary nutritional science identifies carbohydrates, protein, lipids, vitamins, and minerals as the basic elements of a healthy diet, food is often consumed without conscious awareness about its nutritional composition and value or its long-term health implications.^[2,3] A well-balanced diet that offers an adequate amount of all these nutrients is essential for proper nutrition, preserving health, and preventing diseases.^[3] The association between diet and disease has been well-recognized for ages. It is well-established that unhealthy dietary habits or an imbalance in food and drink consumption can contribute significantly to the onset and progression of numerous health problems. Esteemed scholars such as Buqrāt (Hippocrates-460-370 BC), Jālīnūs (Galen – 2nd Century AD), and Ibn Sīna

(Avicenna – 11th Century AD), the pioneers of the Unani medical system, accentuated this connection of diet and disease long before.^[1-4]

The Unani system considers inappropriate dietary practices as a primary contributor to the onset and progression of various diseases. This perspective closely aligns with the contemporary understanding, which links poor nutrition to a wide spectrum of chronic diseases such as diabetes, cardiovascular disease, obesity, metabolic syndrome, hepatic dysfunction, digestive conditions, cancer, and dermatological issues. Excessive intake of saturated fat, refined sugar, and salt, along with low consumption of fiber, fruits, and vegetables, are the major contributors to these conditions.^[1,3] Food, in both the traditional and the modern contexts, has been viewed not only as a sustenance but also as a form of medicine. The concept of *Ilāj bil Taghdhiya* (dietotherapy) in Unani medicine reinforces the therapeutic

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application of food in managing diseases, supporting recovery, and restoring health. This traditional holistic approach is now gaining renewed attention in the contemporary healthcare system, given the ever-increasing evidence on the potential role of dietary interventions in preventing, managing, and even reversing chronic conditions. The diet is now no longer regarded as a secondary measure in treatment; rather, it is increasingly being embraced as a vital element of effective healthcare.^[1]

Unlike contemporary nutritional science, which often stresses solely biochemical components, Unani dietary principles integrate broader determinants such as individuals' temperament, seasonal variations, digestive capacity, psychological character, and environmental factors. These principles advocate a more personalized and dynamic approach to diet, aimed at ensuring harmony between the individual and their surroundings. In Unani medicine, meal timing, food quality and quantity, food combinations, emotional state during eating, and postmeal practices are all regarded as critical for preserving health and preventing diseases.^[5-11] Emerging concepts such as personalized nutrition, chrononutrition, and time-restricted eating resonate strongly with these time-tested Unani principles, underscoring the incessant relevance of traditional dietary wisdom. This review aims to delve into the general dietary principles of Unani medicine, contextualize them within the contemporary scientific paradigm, and explore their potential integration into evidence-based preventive and therapeutic healthcare practices.

Methodology

A comprehensive search was undertaken using bibliographic databases to gather available information on general dietary guidelines. The major databases utilized include PubMed, ScienceDirect, Scopus, and Google Scholar, and the search terms used were dietary principles, food and nutrition, meal timing, time-restricted eating, mindful eating, and personalized nutrition. For insight on general Unani dietary principles, the primary reliance was placed on classical texts available in the library of CCRUM-Central Research Institute of Unani Medicine, Lucknow, and CCRUM-Regional Research Institute of Unani Medicine, Chennai. The key classical works reviewed include, *Kitāb al-Mansūrī* by Muḥammad Ibn Zakariyā Rāzī (865-925 CE), *Al-Qānūn fi'l Ṭibb* by Ibn Sīnā (980-1035 CE), *Firdaws al-Ḥikma fi'l Ṭibb* by Ṭabarī, *Abū al-Ḥasan Raban* (9th Century AD), *Al Mu'ālajāt al-Buqrāṭiyya* by Ṭabarī, *Abū al-Ḥasan Aḥmad Ibn Muḥammad* (10th Century AD), *Kāmil al-Ṣanā'a al-Ṭibbiyya* by Majūsī, *Alī Ibn 'Abbās* (10th Century AD), *Kitāb al-Aghdhiya* by Ibn Zuhr, *'Abd al-Malik ibn Abī al-'Alā* (12th Century AD), *Jāmi' al-Hikmat* by Qarshi, Mohammad Hasan (2011).

Ghidh ā' (diet) in Unani Medicine

The Unani medicine, a holistic healthcare system, stresses the balance of body, mind, and soul. The systems' foundations lie in the Hippocratic doctrine of *Akhalāt Arba'a* (four humors), i.e., *Dam* (blood), *Safrā* (yellow bile), *Balgham* (phlegm), and *Sawdā* (black bile). Health is preserved when these humors remain balanced.^[12-14] The principle of *Asbāb Sitta Darūriyya* (six essential factors) holds vital importance in Unani medicine for maintaining physical, mental, and social well-being, which ensures a balanced lifestyle. Ignorance of these principles disrupts healthy living and eventually results in diseases.^[12,15] Food, among these, ranks as the second most vital factor, which plays a critical role in sustaining life by replenishing the body's worn-out and decomposed components (*Badal Mā Yatahallal*), thereby serving as the foundation of health preservation.^[6,12] *Ilāj bil Taghdhiya* (dietotherapy), one of the core therapeutic strategies in the Unani system, is often employed as the first-line treatment before resorting to pharmacotherapy. Since food directly influences humoral equilibrium, dietary regulation is considered the key strategy for both disease prevention and management.

The concept of *Mizāj* (temperament) is central to Unani dietary practices, which governs personalized dietary choices. In Unani medicine, foods are classified as hot, cold, dry, or moist.^[7] Appropriate dietary choices, aligned with one's innate temperament, not only provide nourishment but also maintain humoral equilibrium, preserve health, and prevent diseases.^[12,15] In general, a healthy individual should preferably consume foods compatible with their innate temperament. However, foods of opposite temperament are advised to restore balance if there is a risk of a pathological shift in the temperament. For example, an individual with a deranged phlegmatic temperament, characterized by excess coldness and moistness, is advised to consume foods having a warm and dry temperament to counterbalance these traits.^[6,7]

Unani scholars constantly considered diet as both a preventive and therapeutic measure, a notion that aligns with contemporary perspectives on the role of nutrition in immunity, disease prevention, and overall well-being. Their intellectual legacy is preserved in numerous classical texts on dietetics, including *Kitāb al-Aghdhiya* (Book on Dietetics) by Ḥunayn ibn Ishāq (9th Century AD), *Kitāb Mā' al-Sha'ir* (Book on Barley Water) by Yuḥannā ibn Māswayh (9th Century AD), *'Manāfi' al-Aghdhiya wa Daf' Maḍarrihā* (Book on the benefits of diets and process of their purification) by Rāzī, *Abū Bakr Muḥammad ibn Zakariyyā* (10th Century AD). Other contributions include *Kitāb al-Aghdhiya* (Book on Dietetics) by Ibn Zuhr, *'Abd al-Malik ibn Abī al-'Alā* (12th Century AD); *Al-Aghdhiya wa'l Ashriba li'l Marḍā* (foods and drinks for patients), and *Al-Aghdhiya wa'l Ashriba li'l Aṣiḥḥā* (foods and

drinks for healthy individuals) by Najībuddīn Samarqandī (13th Century AD); *Al-Mukhtār mina'l Aghdhiya* (selected diets) by Qarshī, 'Alā'uddīn (13th Century AD); and the monumental work '*Kitāb al-Jāmi' li Mufradāt al-Adwiya wa'l Aghdhiya*' (The compendium of single drugs and diets) by Ibn al-Baytār, Diyā'uddīn (13th Century AD), that catalogued over 2300 medicinal materials including various dietary items.^[13,15] These compilations highlight the systematic and comprehensive approach of Unani scholars in integrating dietetics into healthcare delivery. They emphasized the indispensable role of diet in health preservation, disease prevention, and restoration of humoral equilibrium, while offering enduring insights that remain relevant to contemporary understanding of preventive and therapeutic nutrition.

General Unani Dietary Principles and Contemporary Relevance

The Unani medicine places significant emphasis on appropriate dietary habits as a foundation for health preservation and disease prevention. Renowned Unani scholars, including Rāzī, Ibn Sīnā, Rabban Ṭabarī, among others, have articulated well-defined principles governing diet and nutrition. These principles are based on a deeper understanding of temperament, humoral equilibrium, seasonal variations, and the physiological needs of individuals. Unani dietary framework extends beyond the mere selection of food types; it also covers how, when, in what quantity, and in what combination food should be consumed. This holistic approach ensures that diet serves as a natural means of maintaining internal harmony and supporting optimal health. When interpreted in the light of modern nutritional science, these time-tested principles demonstrate exceptional relevance in addressing lifestyle disorders and promoting holistic wellbeing.

Timing, frequency, and quantity of meals

Unani perspective

- Eat only when true hunger is experienced: Food should be consumed only when true appetite is experienced, which is marked by complete digestion of the previous meal, lightness in the lower abdomen, and a natural inclination towards food^[5,8]
- Avoid eating without appetite or delaying food intake despite hunger: Both habits are discouraged, as they may disrupt digestive balance and may lead to the accumulation of morbid matter and digestive disorders^[5,8]
- Number of meals: One or two meals per day are generally recommended for healthy individuals, with the ideal regimen being three meals over 2 days (48 h). Individuals with a weak and dry body constitution may require two meals daily, whereas two meals may be excessive for those with a bulky or fleshy build^[5]

- Moderation in food intake: Overeating must be avoided even in intense hunger;^[5,8] instead, food intake should be moderated to allow one-third of the stomach for food, one-third for water, and one-third for air/respiration as per the guidance of Buqrat (Hippocrates)^[9]
- Refraining from complete fullness: Eating until the stomach is completely full is discouraged as it hampers digestion and may result in the accumulation of waste materials^[8,11]
- Adjusting dietary intake according to activity: Those engaged in strenuous work may require more food, while individuals with a sedentary lifestyle should consume less^[5]
- Regulation of dietary habits: If frequent eating is habitual in an individual, a gradual adjustment of diet should be made to prevent digestive stress and maintain balance.^[5]

Contemporary perspective

Current understanding of nutritional science echoes many of these classical Unani insights. Contemporary research underscores the significance of regular meal timing and advocates eating in response to physiological hunger cues rather than emotional triggers or habitual patterns. Intermittent fasting and time-restricted feeding have gained significant recognition for their metabolic benefits, including weight regulation and improved insulin sensitivity.^[16] Evidences from studies on time-restricted feeding suggest great benefits in aligning meal timings with circadian rhythms, which improves digestive efficiency and metabolic outcomes.^[17,18] Contemporary dietary guidelines usually suggest two to three well-balanced meals per day, while discouraging continuous snacking and frequent small meals, as it may impair insulin sensitivity.^[16] The Japanese practice of "Hara Hachi Bu," which means eating until eighty percent full, is often quoted for its role in longevity.^[19] On the other hand, overeating is closely linked with obesity related pathologies such as inflammation, oxidative stress, and mitochondrial dysfunction.^[20] Moderation in food intake and mindful eating, emphasized in Unani doctrine, are strongly supported by contemporary evidence suggesting their potential role in improving health and longevity.

Eating and emotional state

Unani perspective

Esteemed Unani scholars stated that the emotional state during food intake may negatively influence digestion and overall health. They strongly advocated the thorough chewing of food to ensure adequate mixing with saliva, as it facilitates proper digestion. They cautioned against eating while experiencing sorrow, grief, anxiety, or anger, as these emotional disturbances disrupt the digestive process. Therefore, meals should be taken in a relaxed, calm, and joyful state to promote optimal digestion and wellbeing.^[11]

Contemporary perspective

Modern nutritional science strongly supports this classical wisdom. Scientific evidences highlight a strong association between emotional state, gut function, and metabolic health. Anxiety, depression, stress, and distraction during food intake have been shown to impair gastric function, alter gut motility, and contribute to dysbiosis.^[21,22] Further, food consumption in an emotional state has been linked with many chronic conditions, including metabolic syndrome, diabetes mellitus, obesity, high blood pressure, hypercholesterolemia, ischemic heart disease, and stroke.^[21] In contrast, mindful eating has been associated with improved digestion, reduced stress-related overeating, and better metabolic regulation.^[23]

The Unani principle of maintaining emotional composure during eating finds clear resonance in contemporary nutrition science, corroborating the view that digestion is not only a physical process but also influenced deeply by mental and emotional harmony.

Selection of diet according to *Mizāj* (temperament) and *Mawsam* (season)*Unani perspective*

Aligning diet with the innate temperament of an individual is a fundamental principle of Unani dietary practices. In Unani medicine, foods are classified according to their qualitative attributes, *i.e.*, hot, cold, moist, dry, and dietary selections are primarily guided by their compatibility with one's natural constitution. Consuming foods that harmonize with ones' temperament helps maintain humoral balance and supports overall health. Unani physicians, including Rabban Tabari and Ibn Sina, observed that digestive capacity varies with seasonal changes. During winter, due to increased internal warmth and prolonged sleep, digestive strength is enhanced, allowing for the consumption of heavier and more nutritious meals. Conversely, in summer, lighter, moist, and cooling foods are recommended to prevent heat-related disturbances and maintain equilibrium.

Key principles

- Food should be selected according to an individual's temperament, and only those foods should be consumed that attract and are suitable to the individual's *Tabi'at* (nature)^[5,8]
- In summer, moderately cold and moist foods are preferred, while in winter, warm and nutritious foods are advised^[6,8]
- Light, low-nutritive foods and vegetables should be minimized in cold weather, particularly for individuals with a weak constitution^[8]
- In a hot climate, light, easily digestible, and hydrating foods are ideal^[8]
- Seasonal adaptation: In winter and autumn, when digestive power is strong, food intake may be increased,

while in summer, smaller and more frequent meals with cooling beverages are beneficial.^[6,8]

Contemporary perspective

The concept of personalized nutrition is being increasingly embraced by contemporary nutritional science, while recognizing that the genetic polymorphism, gut microbiota profile, and metabolic phenotypes greatly influence dietary responses. Nutrigenomic and nutrigenetic models, that tailor diets to the physiological and metabolic profile of an individual, are now replacing the traditional dietary approach of "one size fits all." Contemporary research supports personalized nutrition based on postprandial glycemic responses, metabolic flexibility, and gene-diet interactions.^[24,25]

Seasonal adaptation of diets is advocated in both Unani and modern frameworks. Contemporary guidelines recommend warm, calorie-dense foods in cold seasons to support thermogenesis and energy needs, whereas, in summer, light meals, hydration, and cooling foods are prioritized. These seasonal shifts reflect physiological variations in metabolic rate, hormonal regulation, and digestive efficiency.^[26,27]

Thus, the Unani doctrine of selecting diets in accordance with the temperament of an individual and the season strongly resonates with the contemporary understanding of individualized and seasonally adaptive nutrition.

Food quality, freshness, and preparation*Unani perspective*

Unani scholars underscored that the quality and freshness of food play a crucial role in maintaining digestive health and preventing temperamental derangement. They recommended consumption of freshly prepared foods, and cautioned against eating excessively hot, stale, or spoiled meals, as these may cause disruption in digestive capacity and produce harmful humors. Similarly, the consumption of old or stagnant water, particularly that stored for more than 6 days, was also discouraged due to its negative impact on digestion and vitality.^[5,11] According to the Unani perspective, the preparation of food should be simple, clean, and it should be compatible with the season and the temperament of the individual. Proper cooking is encouraged, as it enhances the nutritive value of food and facilitates assimilation, while overcooking and prolonged storage are discouraged as they diminish the quality of food and may lead to the accumulation of morbid materials in the body.^[7,11]

Contemporary perspective

Contemporary guidelines mirror this classical understanding by highlighting the importance of fresh food, minimal processing, and safe cooking practices. Current dietary guidelines encourage consuming fresh, home-cooked meals and discourage reliance on processed and ultra-processed

items, as these are closely associated with an increased risk of obesity, cardiovascular diseases, metabolic disorders, and gastrointestinal dysfunction.^[28] Prolonged storage of food, frequent reheating, and excessive use of preservatives during food processing can potentially degrade nutrient quality and produce harmful components such as advanced glycation end-products and oxidized lipids, which are known to contribute to oxidative stress and inflammation.^[29] In this context, the emphasis of Unani medicine on freshly prepared, wholesome food remains significantly relevant, aligning seamlessly with contemporary nutritional recommendations for promoting digestive health and overall well-being.

Food combination and sequence

Unani perspective

Esteemed Unani scholars have stressed moderation in food consumption and harmony in food combinations to preserve digestive capacity and humoral equilibrium. Rāzī, Ibn Sīnā, and Qarshī, have cautioned against consuming various types of foods in a single meal, particularly combining heavy foods with light ones, as it burdens the digestive faculty and may lead to the production of morbid humors. It is advocated that the meal should be taken in a reasonable time frame without prolonging the eating duration, as delayed eating or eating for an extended duration may disrupt the sequential stages of digestion. Unani doctrine further advocates that fruits should be consumed before a meal, as they aid in digestion. However, sour and astringent fruits can be consumed after a meal. Nonetheless, consuming fruits or light foods after a heavy meal may lead to fermentation and indigestion. Further, hard and indigestible foods are discouraged even for those with strong digestive capacity, as they can accumulate in the body and gradually give rise to chronic conditions.^[5,8,11]

Key guidelines

- Avoid mixing different types of foods in one meal, particularly heavy with light foods
- Consume lighter foods before heavier ones for proper sequential digestion
- Avoid prolonged meal durations and improper combinations that may hinder digestion
- Refrain from eating hard or indigestible items, even with strong digestion.^[5,6]

Contemporary perspective

Current nutritional science corroborates these principles, underscoring that well-sequenced and simplified meals improve digestive efficiency and metabolic outcomes. Research findings indicate that the order of food intake influences postprandial responses, such as consumption of vegetables before carbohydrates can improve glycemic control and insulin responses, and sequential consumption of vegetables, protein, and carbs improves metabolic

responses.^[30] Fruit intake before a meal has shown significant enhancement in satiety.^[31] This scientific evidence resonates with the Unani view that the proper sequence and compatibility of foods are essential for maintaining digestive harmony and overall metabolic health.

Fluid intake practices

Unani perspective

The Unani principles consider moderation and timing in fluid intake as an essential component for maintaining digestive health. Water consumption should generally be avoided during meals, as it dilutes gastric juices, alters internal temperament, and interferes with the digestive process. During a meal, only a few sips of water may be taken if necessary. Cold or iced water is considered *Ghalīz* (dense), and is believed to weaken digestive power, especially when taken immediately after a meal. Such water may be tolerated by individuals with a predominantly hot temperament, and even then, in small quantities. Unani scholars also cautioned against the consumption of water immediately after physical exertion or during states of excessive hunger, as it can lead to serious disturbances such as indigestion, muscle weakness, or even fainting, particularly in the elderly or weak individuals. Stale or stored water (kept for more than 6 days) is discouraged, as it loses freshness and may become harmful to the natural faculties.

Key guidelines

- Water should generally not be consumed during meals; an interval of about 2–3 h after eating is ideal for proper digestion. If necessary, only a few sips may be taken during a meal to moisten the throat^[11]
- Cold or iced water, being *Ghalīz* (dense), should be avoided, particularly after meal, as it can impair digestion and produce viscous humors^[8,9]
- Individuals with a cold temperament should especially avoid cold or iced water^[9]
- Fresh and clean water is preferred; stored water beyond 6 days should not be consumed^[9]
- Water consumption, immediately after strenuous activity, should be avoided, particularly in weak and elderly individuals, as it may negatively impact health and wellbeing.^[11]

Contemporary perspective

Current guidelines support the Unani doctrine of fluid intake practices. It is suggested that consuming fluid in large quantities, especially cold beverages, during or immediately after meals may delay gastric emptying and reduce enzymatic activity, potentially leading to bloating and indigestion. Water consumption is advocated between meals rather than during meals, and room-temperature fluids are preferred for better digestive health. However,

studies suggest that consuming 1–2 glass of water during a meal results in weight loss. Excessive water intake is associated with a lower energy intake, satiety, and obesity prevention.^[32] Hence, obese individuals may consume water during meals to improve satiety, decrease energy intake, and ultimately reduce their body weight.

Postmeal practices

Unani perspective

Appropriate postmeal practices are considered vital in Unani medicine for ensuring proper digestion and maintaining humoral equilibrium. Unani scholars such Rāzī, Ibn Sīnā, and Qarshī have advocated that, after a meal, the body should be allowed to direct its vital energy towards digestion without being diverted by strenuous physical or mental activity. Rest, light recreation, or gentle movement after meals helps the stomach perform its function efficiently.

Key guidelines

- A light nap after lunch is beneficial for digestion, restoration of body energy, and mental relaxation
- A gentle walk after dinner (about 100–200 steps) aids digestion and facilitates evacuation of flatus, thereby improving sleep quality and metabolic balance
- Strenuous physical activities such as running, horse riding, wrestling, or coitus should be avoided immediately after meals, as they divert blood flow away from the digestive organs, leading to indigestion and the formation of impure humors
- Sleeping immediately after meals should be avoided; instead, one should allow sufficient time for partial digestion before lying down
- Sleeping on an empty stomach is also discouraged, especially in weak or lean individuals, as it may cause depletion of *Harārat Gharīziya* (innate heat) and humoral imbalance
- Maintaining a calm and cheerful mood after a meal is encouraged, as anger, grief, or anxiety immediately after eating can impair digestion.^[9,11]

Contemporary perspective

Contemporary advice mirrors many of these Unani postmeal practices. Studies have shown that light walking after meals enhances gastric motility, reduces postprandial blood glucose levels, and improves overall glycemic control.^[33] Similarly, short, early-afternoon naps (10–30 min) have been found to enhance alertness, cognitive performance, and cardiovascular health.^[34] On the other hand, strenuous activity immediately after a meal and prolonged sitting are associated with reflux, bloating, and metabolic disturbances. Thus, both contemporary and Unani recommendations emphasize the significance of moderation, gentle movement, and mental relaxation after a meal for optimal digestion and wellbeing.

Conclusion

The Unani system of medicine presents a time-tested and integrative approach to diet that remains notably relevant in the era of precision and lifestyle medicine. Its dietary principles are rooted in the recognition of physiological variations in individuals, underscoring differences in their temperaments, environment, season, and their emotional states as critical determinants of health. The focus of Unani medicine on moderation in food quantity, meal timing, mindful eating, and seasonal adaptation finds substantial support in contemporary nutritional research on metabolism, gut health, and circadian regulation. Further, principles such as avoiding overeating, ensuring food freshness, and maintaining calmness during and after meals resonate with contemporary insights into digestive physiology and psychosomatic health.

Unani scholars, by underscoring food as both sustenance and therapy, laid the foundation for many principles that are currently central to *Ilāj bil Taghdhiya* (dietotherapy), preventive medicine, and metabolic health management. The convergence of Unani wisdom with contemporary scientific paradigms such as personalized nutrition, nutrigenomics, and integrative medicine underscores its relevance for addressing lifestyle disorders. Adapting these Unani doctrines within an evidence-based framework may enhance the potential of dietary interventions that are culturally sensitive, individualized, and physiologically sound.

To conclude, aligning Unani dietary principles with modern nutritional science presents an integrative model, amalgamating traditional wisdom with empirical rigor. Such integration not only enriches the scientific understanding of diet and health but also supports the global movement toward comprehensive, preventive, and person-centered healthcare that harmonizes traditional wisdom with the contemporary scientific landscape.

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Conflicts of interest

There are no conflicts of interest.

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Unani Perspective of PCOS with Special Reference to the Potential Benefits of *Satāwar* (*Asparagus racemosus* Willd.) for Women's Reproductive Health

Abstract

Polycystic ovary syndrome (PCOS) is one of the most common endocrine and metabolic disorders affecting women of reproductive age, characterized by hormonal imbalance, irregular menstruation, anovulation, and *Uqr* (infertility). Despite multiple therapeutic options in modern medicine, the management of PCOS remains largely symptomatic and often associated with adverse effects. The Unani system of medicine offers a holistic approach that addresses the underlying imbalances of humors (*Akhlāṭ*) and temperament (*Mizāj*), emphasizing detoxification, hormonal modulation, and restoration of reproductive health. Among the classical Unani drugs, *Asparagus racemosus* Willd. (*Satāwar*) holds a prominent position as a potent uterine tonic, emmenagogue, galactagogue, and aphrodisiac. To review and highlight the therapeutic potential of *Asparagus racemosus* (*Satāwar*) in the management of Polycystic Ovary Syndrome from a Unani perspective and contemporary pharmacological evidence by correlating classical Unani concepts with modern scientific understanding, exploring its phytochemical and pharmacological profile, and evaluating experimental and clinical studies supporting its efficacy. A comprehensive literature review was conducted using classical Unani texts and modern scientific databases, including PubMed, Scopus, Web of Science, and Google Scholar. Keywords such as “*Asparagus racemosus*, *Satāwar*, Unani Medicine, PCOS, reproductive health, and phytoestrogen” were used to retrieve relevant preclinical and clinical studies published in English and Urdu. Preclinical studies revealed that *Asparagus racemosus* regulates hormonal balance, reduces hyperandrogenism, and promotes follicular development. Clinical trials demonstrated its effectiveness in normalising menstrual cycles, enhancing ovulation, and improving metabolic parameters in women with PCOS. The presence of phytoestrogens, flavonoids, and saponins contributes to its hormonal and reproductive benefits. The findings support Unani claims of *Satāwar* as a safe and effective therapeutic option in managing PCOS, warranting further controlled clinical research to establish evidence-based integration in modern reproductive healthcare.

Keywords: *Asparagus racemosus*, polycystic ovary syndrome, *Satāwar*, Unani medicine

Introduction

Women between the ages of 15 and 49 are frequently examined and diagnosed with Polycystic ovary syndrome (PCOS), as this is the period when hormonal imbalances, menstrual irregularities, and fertility concerns become most apparent. PCOS is a heterogeneous disorder that consists of a combination of signs and symptoms of androgen excess and ovarian dysfunction in the absence of another specific diagnosis.^[1,2] A significant risk association has been reported with abdominal adiposity, insulin resistance, metabolic and cardiovascular disorders. Scientific evidence suggests that PCOS is a complex

polygenic disorder with strong epigenetic and environmental influences, including diet and lifestyle factors that vary widely among individual patients.^[2,3] This gynecological disorder has attained huge magnitude as the World Health Organization estimated 8%–13% of reproductive-aged women are affected by PCOS, and up to 70% of affected women remain undiagnosed worldwide.^[3] The prevalence rate of PCOS is high among Indian women. In India, the reported prevalence varies between 5.8% and 22.5%, reflecting significant regional and diagnostic variability.^[4,5] However, the diagnostic criteria for PCOS were different in those studies. The prevalence of PCOS is higher among some ethnicities, and these

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groups often experience more complications, particularly related to metabolic problems. The biological and psychological effects of PCOS, particularly those related to obesity, body image, and *Uqr* (infertility), can lead to mental health challenges and can also lead to anxiety, depression, and social stigma.^[3]

Symptoms of polycystic ovary syndrome can differ from person to person, may change over time, and often occur without a clear trigger. The possible symptoms are menstrual irregularities (polymenorrhea, oligomenorrhea, and *Ihtibas-al-tamth* [amenorrhea]), acne, hirsutism, acanthosis nigricans, alopecia, hoarseness of voice, weight gain, mood swings, and *Uqr* (infertility). PCOS women are more likely to have associated health conditions such as type 2 diabetes, hypertension, dyslipidemia, heart disease, and endometrial cancer.^[1,3,4]

Mainstream treatment of PCOS primarily focuses on symptomatic management rather than addressing the root cause of the disorder. Oral contraceptive pills are commonly prescribed to regulate menstrual cycles and suppress androgenic symptoms; however, long-term use is associated with adverse effects such as weight gain, mood changes, liver toxicity, and an increased risk of thromboembolism.^[6-9] Insulin-sensitizing agents like metformin, though beneficial in improving insulin resistance and metabolic parameters, frequently cause gastrointestinal discomfort and exhibit limited efficacy in certain PCOS phenotypes—especially those not predominantly driven by metabolic dysfunction.^[3,9,10] Moreover, these agents fail to restore spontaneous ovulation or correct underlying hormonal imbalances once discontinued, often leading to recurrence of symptoms.^[8] In cases of *Uqr* (infertility), options include clomiphene citrate, ovarian drilling through laser treatment, and assisted reproductive techniques.^[11] For managing hirsutism and acne, medications such as cyproterone acetate, ethinylestradiol, and spironolactone can be effective.^[1,2,12] These therapeutic limitations^[6,7] have led to increasing global interest in traditional and alternative therapies that are safer, holistic, and capable of addressing multiple pathophysiological aspects of the disorder.^[13-16]

The Unani system of medicine, with its holistic and humoral principles, offers a complementary approach to PCOS management. It conceptualizes the disorder as a manifestation of deranged temperament (*Sū'-i-Mizāj*) and humoral imbalance, particularly the predominance of phlegm (*Balghami*), which affects hepatic and reproductive functions.^[17-20] Unani therapy focuses on detoxification, correction of humoral imbalance, and restoration of reproductive health through herbal formulations with proven safety and efficacy. Among these, *Asparagus racemosus* (*Satāwar*) is a well-documented Unani drug valued for its uterine tonic, emmenagogue, galactagogue, and aphrodisiac properties.^[19,21-23] Modern pharmacological investigations have demonstrated that *Asparagus*

racemosus contains bioactive compounds—such as steroidal saponins (shatavarins), flavonoids, and isoflavones—that exert phytoestrogenic, antioxidant, and anti-inflammatory effects. These actions may contribute to improved follicular development, hormonal balance, insulin sensitivity, and ovulatory function in PCOS.^[24-29] Therefore, integrating Unani therapeutics like *stawar* (*Asparagus racemosus*) with contemporary clinical understanding provides a rational, evidence-based approach to overcoming the limitations of conventional therapies and addressing PCOS more comprehensively and sustainably.

Materials and Methods

A comprehensive literature search was conducted to gather relevant studies on the impact of *Asparagus racemosus* on reproductive health in women with polycystic ovary syndrome (PCOS), with a special focus on Unani and modern perspectives. The review process involved a systematic and structured search of both classical Unani literature and modern scientific databases. The primary databases searched included PubMed, Scopus, Web of Science, Science Direct, and Google Scholar. Classical Unani texts such as *Al-Qanoon fil Tibb*, *Al-Hawi fit Tibb*, *Zakheera Khawarzam Shahi*, and *Kamilus Sana* were also reviewed for Unani classical references. The search terms used were a combination of keywords and phrases such as “*Asparagus racemosus*,” “asparagus,” “Satavar,” “*Satāwar*,” “*Shatavari*,” “*Shatawari*” “Polycystic Ovary Syndrome,” “PCOS,” “reproductive health,” “fertility,” “hormonal balance,” “Unani Medicine,” and “natural remedies.” The studies were included if they were published in English or Urdu and involved experimental (*in vitro* or *in vivo*) or clinical research assessing *Asparagus racemosus* in the context of reproductive, hormonal, or metabolic issues related to polycystic ovary syndrome (PCOS). Eligible studies had to evaluate pharmacological, phytochemical, or endocrine-modulating effects. Clinical investigations needed at least ten participants and a treatment period covering two or more menstrual cycles. Only articles from peer-reviewed journals or other reputable academic sources were accepted. Editorials or commentaries without original research and studies of multi-herbal formulations were also excluded if they did not clearly identify the role of *Asparagus racemosus*. Duplicate studies and unpublished works lacking verifiable methods were not considered.

Observations

PCOS in the Unani system of medicine

polycystic ovary syndrome (PCOS) being originally described by Stein and Leventhal in 1935,^[30] a relatively new entity to classical ancient knowledge and in classical Unani literature it is not mentioned as PCOS, but the clinical picture mimics the description mentioned in ancient Unani classics which is a combination of symptoms such as *Ihtibas-al-tamth* (amenorrhea), *Qillat-I tamth*

(oligomenorrhea), *Uqr* (infertility), obesity, hirsutism (excessive hair growth), acne, and hoarseness of voice very much suggestive of polycystic ovary syndrome (PCOS).^[17-19] According to the Unani system of Medicine, these symptoms occur due to an abnormal production of *Balgham* (phlegm), which in turn is caused by the phlegmatic temperament of the liver. This leads to the accumulation of abnormal *Balgham* (phlegm) in the body, altering the temperament and giving rise to various symptoms such as *Ihtibas-al-tamth* (amenorrhea), *Uqr* (infertility), and obesity. The alteration of the normal temperament and the predominance of *Balgham* (phlegm) in the body of females is considered a central dogma for hirsutism, cyst formation in the ovaries, obesity, and *Ihtibas-al-tamth* (amenorrhea), which leads to PCOS.^[17-20] The Unani system of medicine has a detailed description of several effective and safe drugs that can be used successfully to resolve the cyst and prevent surgical intervention. The treatment has been recommended holistically, and the drugs that have been mentioned usually are emmenagogue, aphrodisiac, uterine tonic, and general tonic in action, and also possess concoctive and *Balgham* (phlegm) expulsive properties.

Treatment of PCOS in Unani system of medicine

The treatment of PCOS in the Unani system of medicine is addressed holistically and is discussed under the heading of *Amrād-i-Niswān* (gynecological disorders). Many Unani formulations have been used for centuries to address different gynecological disorders. The main aim of Unani treatment in women with PCOS is (a) Detoxification and moderation of the humor and temperament of the body through *Munḍij wa Mushil* therapy, (b) Strengthening and revitalizing the female reproductive system and regularizing menstrual cycles, and (c) To correct the hormonal imbalance by using Unani medicines.^[13,17-20]

Recent clinical studies^[13-16,31] indicate that Unani medicine may be particularly effective for specific phenotypes of polycystic ovarian syndrome (PCOS) that are challenging to manage with allopathic treatments.^[32] This is especially true for cases characterized by chronic inflammation, obesity, and insulin resistance. The studies emphasize the efficacy of herbal-based Unani formulations in restoring hormonal balance and inducing ovulation, which can be particularly advantageous for patients with androgen-dominant PCOS.^[33-36] Unani medicine adopts a holistic approach to PCOS by focusing on balancing bodily humors (*Akhlāt*), detoxifying the system, and regulating hormones. While allopathic treatments such as Metformin may lead to gastrointestinal issues, Unani formulations aim to enhance metabolism naturally. For instance, *Safūf-e-Mohazzil* (Anti-obesity powder) aids fat metabolism and improves digestive health.^[37,38] Unlike allopathic approaches that often rely on oral contraceptives which can pose long-term side effects like weight gain and mood swings,^[39,40] Unani medicine seeks to restore natural ovulation.^[21,41]

The Unani drugs that correct the *Sū'-i-Mizāj Bārid* (cold morbid temperament), amenorrhea, regulate menstrual cycles, and *Uqr* (infertility), are generally found to be useful in PCOD.^[18-20] Various Unani single drugs, such as *Abhal*, *Badiyan*, *Aspand*, *Hab Balsan*, *Hab Khurtum*, *Habbul Qilt*, *Reward Chini*, *Akleelul Mulk*, *Tukhm Kasus*, *Kharkhask*, *Parsiya-o-Shan*, *Jadwar*, and *Akarkarha*, are generally used in the management of *Ihtibas-al-tamth* (amenorrhea) and *Uqr* (infertility).^[22,42,43] Compound Unani formulations such as *Sharbat Ersa*, *Sharbat Sikanjabīn Asali*, *Ma'jūn Dabīd al-ward*, and *Ma'jūn Muqawwī-i-Rahīm* are also used.^[18,42,44] Moreover, the hepatoprotective^[45-49] nature of these drugs can correct the hormonal imbalance due to PCOS since most of these drugs^[50-52] also contain phytoestrogens that mimic the estrogenic action and normalize the menstrual cycle. These drugs also have the properties of *muḥallil-i-awrām* (anti-inflammatory), *mufattiḥ* (vasodilators), *mudirr-i-bawl wa mudirr-i-hayḍ* (diuretic and emmenagogue), *mulaṭṭif*, *musakkin-i-alam* (analgesic), *muqawwī-i-mi'da wa jigār* (tonic to stomach and liver), *muqawwī-i-dimāgh* (brain tonic), and *muqawwī-i-bāh* (aphrodisiac).^[19,22] All these drugs come in the first degree of hot and dry temperament, possessing a moderate degree of *harāra* (hotness) and *Yubūsat* (dryness), which is suitable for *Ihtibas-al-tamth* (amenorrhea) and *Uqr* (infertility) caused by *sū'-i-mizāj bārid*.^[22] The treatment options available in modern medicine can only improve the symptoms, and several alternative therapies have been found effective in managing PCOS. The safety and promising effects of herbal treatments in PCOS management have led researchers to further explore the potential of these drugs in the management of PCOS. Therefore, the present paper aims to review the effectiveness of one of the well-known drugs, *Satāwar* (*Asparagus racemosus*), which has been recommended for the management of PCOS in the Unani system of Medicine.

Satāwar (*Asparagus racemosus*)

Asparagus racemosus (*Satāwar*) [Figure 1] is an indigenous medicinal plant of the family Liliaceae.^[23] The distribution of this species is throughout the tropical and subtropical zones. The species from various locations frequently differ in their chemical contents and constituents.^[53] Rhizomes and tuberous roots in *Asparagus racemosus* are barely noticeable in the summer, and the aerial section of the plant goes dormant.^[54]

Action and Use as Per the Unani System of Medicine

Asparagus racemosus possesses various medicinal properties, including refrigerant, nutritive, demulcent, galactagogue, tonic, diuretic, aphrodisiac, antispasmodic, antidiarrheal, and antidyenteric effects. In addition, its medicated oil is commonly used to treat nervous and rheumatic disorders.^[18,19,32]

Therapeutic Uses in the Unani System of Medicine^[19,22,24,25,42,55]

In the Unani system of medicine, *Satāwar* (*Asparagus racemosus*) is revered for its ability to combat a wide range of disorders, each reflecting its profound therapeutic applications. In Unani system of Medicine *Satāwar* (*Asparagus racemosus*) is used in various disorders like *amrād-i-kulya wa jigār* (diseases of kidney and liver), *bawāsīr* (piles), *ishāl* (diarrhea), *jarayān* (semenorrhoea), *sur'a al-inzāl* (premature-ejaculation), *mughalliz-i-manī* (semen inspissant), *mugharrī* (glueing), *mukhrij-i-balgham* (expectorant), *musakkin* (analgesic), *muqawwī-i-bāh* (aphrodisiac), *niqris* (gout), *sayalān al-raḥim* (leucorrhoea), *intithār al-sha'r* (hair loss), *waja' al-mafāšil* (arthritis), and *zahīr* (dysentery).

Biodynamic Constituents

Asparagus racemosus (*Satāwar*) contains a diverse range of bioactive phytochemicals that contribute to its various pharmacological activities.

Saponins and saponinins

Satāwar contains steroidal saponins, including shatavarins (I-IV), sarsasapogenin, adscendin, and asparanin, among others. These compounds exhibit diverse pharmacological effects, including uterine tonic properties and potential inhibition of oxytocin-induced contractions, modulating hormone levels, and exerting estrogenic effects. *Shatavarins* (the primary phytoconstituents of *Satāwar*) have been contributing to its traditional use as a galactagogue and managing hormonal imbalances. They may help regulate hormonal levels, potentially addressing some symptoms associated with PCOS, such as irregular menstruation and hormonal imbalances.^[26-29]

Flavonoids

Satāwar flavonoids such as quercetin, rutin, and hyperoside, which have been isolated from different parts of the plant, possess antioxidant and anti-inflammatory properties. Flavonoids, due to their antioxidant and anti-inflammatory properties, may help alleviate some symptoms of PCOS and improve overall health.^[27-29,55-59]

Isoflavones

Satāwar contains isoflavones like 8-methoxy-5,6,4'-trihydroxyisoflavone-7-O-β-D-glucopyranoside and has been identified in the roots.^[26,27,27-29] These compounds may contribute to *Satāwar*'s as a hormone modulator and its traditional use in managing conditions related to hormonal imbalances, such as PCOS and menstrual irregularities. Asparagine A has been isolated from the ethanol extract of the roots. Diosgenin, a saponin, has been found in the leaves.^[55-59]

Polysaccharides and mucilage contribute to *Satāwar*'s emollient and soothing properties, which may be beneficial

in conditions such as diarrhea and inflammatory disorders and may help alleviate gastrointestinal discomfort. The gut microbiome and polycystic ovary syndrome (PCOS) are strongly linked, according to research. Women with PCOS frequently have “dysbiosis” (imbalance) in their gut bacteria, which may exacerbate the symptoms of the condition, such as inflammation, insulin resistance, and hormonal irregularities. This suggests that changes in the diversity and composition of gut bacteria may play a role in the development of PCOS.^[60-63]

Satāwar also contains essential oils, amino acids such as asparagine, arginine, and tyrosine, vitamins (A, B1, B2, C, and E), minerals (magnesium, phosphorus, calcium, and iron), and folic acid, which collectively contribute to its nutritive and therapeutic properties.

Role of *Satāwar* in the Reproductive Health of Women in PCOS

Satāwar has been successfully used in the management of PCOS in the Unani system of Medicine due to its ovulation-inducing (*muwallid-i-manī*) and aphrodisiac (*muqawwī-i-bāh*) characteristics, as well as the fact that it is known to contain phytohormones (steroidal saponins and glycosides) such as shatavarins (I-IV), sarsasapogenin,^[27,29] the precursor of many pharmacologically active steroids. *Satāwar* has been found efficient in promoting follicular growth and ovulation. It helps promote the normal development of ovarian follicles, regulates the menstrual cycle, and revitalizes the female reproductive system, mainly due to its phytoestrogen (natural plant-based estrogen). It also helps in combating hyperinsulinemia.^[26,54,62] *Asparagus racemosus* has been reported to have pharmacological effects in various disorders such as nervous disorders, dyspepsia, tumors, inflammation, neuropathy, hepatopathy, antiulcer, antioxidant, antidiarrheal, immune-modulatory activities, prevents ageing, increases longevity, and improves mental function.^[34]

Preclinical Studies

Several preclinical studies have been carried out on the effect of *Satāwar* in the management of PCOS [Table 1]. It has been reported by Masilamani, Sri Devi, et al. that *Asparagus racemosus* reduced hyperglycemia and hyperandrogenism *in vitro* and *in silico* experiments and, therefore, can be considered as a potential drug for the management of PCOS.^[64] Jashni, Hojatollah Karimi, et al., in a study, reported that *Asparagus* stimulates the secretion of hypothalamic–pituitary–gonadal axis hormones and also improves the process of oogenesis and increases the number of follicles in female rats.^[65] In another animal study, Hamed RS reported that *Asparagus racemosus* improves pubertal mammary gland development, increases milk yield, and enhances the productivity of rabbit does.^[66] Kaaria LM studied the effect of *Asparagus racemosus* on the female reproductive cycle using the Wistar rat model

Table 1: Preclinical studies on *Satāwar* (*Asparagus racemosus*) involved in polycystic ovary syndrome management

Study title and reference	Drug/ intervention	Experimental model	Methodology	Results	Key findings
<i>A. racemosus</i> -A potential PCOD healer through the management of hyperglycemia and hyperandrogenism, An <i>In vitro</i> and silico approach ^[64] (2023)	Ethanolic Extract of the root powder of <i>A. racemosus</i> and the standard drug (Acarbose)	<i>In vitro</i> antidiabetic activity	α -amylase enzyme-inhibiting effect Inhibitory action of Glucose diffusion Glucose uptake by yeast cells	<i>A. racemosus</i> inhibited α -amylase enzyme at a low concentration compared to the control Acarbose. The IC ₅₀ value for the study is 367 μ g/mL <i>A. racemosus</i> inhibited the glucose diffusion at all given concentrations, and an enhanced activity is observed at higher concentrations of 1000 μ g/mL The plant extract-treated yeast cells showed a concentration-dependent increase in glucose uptake. This shows that the phytochemicals present in the ethanolic extract of <i>A. racemosus</i> mimic the action of insulin, thereby aiding in the entry of glucose molecules inside the yeast cells Irrespective of the glucose concentration, the drug could combine with glucose and slow down absorption in the intestines In the patch dock analysis, five ligands, namely Quercetin, Racemosol, Rutin, Hyperoside, and <i>Shatavarin</i> I, were selected as the best antagonistic ligands for the IRS1 and IRS2 receptors in terms of their docking score and amino acid interactions And thus exerting the anti-hyper-androgenic effect	<i>In vitro</i> and <i>in silico</i> studies of <i>A. racemosus</i> can address hyperglycemia and hyperandrogenism, which are interconnected complex aspects of PCOS pathophysiology
<i>A. racemosus</i> ^[64]		<i>In silico</i> antidiabetic activity <i>In silico</i> anti-hyperandrogenic activity	Glucose adsorption potential by plant extract Molecular docking using PatchDock analysis to screen suitable antagonistic phyto ligand from the plant for the IRS1 and IRS2 receptors for the negative down-regulation of androgen production. The inhibitory activity of the receptors IRS1 and IRS2 with the phytochemicals of <i>A. racemosus</i> was performed using Ligplot	The selected phyto-molecules present in <i>A. racemosus</i> act as potential antagonistic ligands for the receptor IRS1 and IRS2, which regulate the synthesis of androgens in the ovary	
Effect of <i>A. racemosus</i> on selected female reproductive parameters using the Wistar rat model ^[67]	Aqueous extract of <i>A. racemosus</i> Ibuprofen (positive control) Physiological saline (negative control)	Nulliparous nonpregnant normal cyclic Female albino Wistar rats 5–6 weeks old Plant extract every other day for 14 days. (600 and 300 mg/kg, respectively)	Female reproductive parameters Estrus cyclicity, mating success Gestation length Litter size Dysmenorrhea, Isolated uterine strip contraction Acute oral toxicity was done to determine the lethal dose (LD50) and the safety of the plant extract	The treated groups show Significant increase in the proestrus phase ($P < 0.001$) Subsequent significant reduction in the metestrus ($P < 0.01$) and diestrus ($P < 0.05$) Produced a higher number of pups Significant reduction in uterine force and the frequency of contraction The extract caused no mortality even at the limit dose of 5000 mg/kg	<i>A. racemosus</i> may be used for the fertility effect and dysmenorrhea management. It showed no adverse effects and can be used as a fertility promoter

Contd...

Table 1: Contd...

Study title and reference	Drug/intervention	Experimental model	Methodology	Results	Key findings
Effects of aqueous extract from <i>Asparagus officinalis</i> L. roots on hypothalamic-pituitary-gonadal axis hormone levels and the number of ovarian follicles in adult rats ⁽⁶⁵⁾ (2016)	Aqueous extract of asparagus roots, in three doses (100, 200, 400 mg/kg/BW) for 28 days	In vivo - 40 adult female Wistar rats were divided into five groups: Three experimental groups, one control, and one sham	Evaluation of serum levels of GnRH, FSH, LH, estrogen, and progesterone hormones Microscopic examination of ovaries	Significantly increased serum GnRH, FSH, LH, oestrogen, and progesterone levels Increase in the number of ovarian follicles and corpus luteum, compared to control and sham groups. ($P < 0.05$)	<i>A. officinalis</i> stimulates the process of oogenesis. Consequently increases the number of follicles and ovarian hormones
Effects of aqueous extracts of <i>G. officinalis</i> and <i>A. racemosus</i> supplementation on the development of mammary gland, milk yield, and its impact on the productivity of rabbit does ⁽⁶⁶⁾ (2016)	Aqueous extract of roots of and Dried aerial parts of <i>G. officinalis</i> and <i>A. racemosus</i> supplementations in drinking water Supplemented throughout rearing period and the gestation period, and the first 21 days of lactation	60 Female V-Line breed rabbits aged 10 weeks old (rabbit does) 1st group (control) 2nd and 3rd groups (<i>Galega officinalis</i>) of 150 and 300 mg/kg BW, respectively 4th and 5th groups (<i>A. racemosus</i>) of 100 and 200 mg/kg BW, respectively	Supplemented throughout the rearing period and continuously for the full duration of the gestation period and the first 21 days of lactation Histometric Measurements of the Mammary gland of the rabbit do Milk yield and its impact on the productivity of rabbit does	Both the plant extracts showed a significant increase in Ovarian hormones (oestrogen and progesterone) Surface area of the mammary alveoli Pubertal mammary gland development Milk yield Productivity of rabbit does A high level (200 mg/kg BW) of <i>A. racemosus</i> during pregnancy significantly increased stillborn at birth	Aqueous extract from both <i>G. officinalis</i> and <i>A. racemosus</i> improved mammary gland development, milk yield, and productivity of rabbit does <i>A. racemosus</i> should be avoided during the pregnancy of rabbit does
Effect of <i>A. racemosus</i> rhizome (Shatavari) on mammary gland and genital organs of pregnant rat ⁽⁶⁸⁾ (2005)	The alcoholic extract of the <i>A. racemosus</i> rhizome	Orally to adult pregnant female albino rats at a dose of 30 mg/100 g body weight, daily for 15 days (1-15 of gestation) The control animals received 1 mL drug-vehicle (10% of Tween-80 in water)	The mammary glands and the vaginal orifice of both groups were observed on day 15 of gestation for any change in shape, size, and colour. The animals were killed on day 16 of pregnancy for the macro and microscopic examination	In the treated group of animals Macroscopic findings revealed Prominence of the mammary glands Dilated vaginal opening Increase in the weight of the uterine horn Microscopic examination showed Proliferation in the lumen of the duct of the mammary gland. Obliterated due to hypertrophy and Hyperplasia of ductal and glandular cells Parenchyma of the genital organs showed abundant glycogen granules with dilated blood vessels and thickening of the epithelial lining Oviduct showed a hypertrophied muscular wall, whereas the ovary revealed no effect of the drug	The results suggest an oestrogenic effect of <i>Satāwar</i> on the female mammary gland and genital organs

IRS: Insulin Receptor Substrate 1, GnRH: Gonadotropin-releasing hormone, FSH: Follicular-stimulating hormone, LH: Luteinizing hormone, A officinalis: *Asparagus officinalis*, *G. officinalis*: *Galega officinalis*, *A. racemosus*: *Asparagus racemosus*, BW: Body weight, PCOS: Polycystic ovary syndrome, PCOD: Polycystic ovarian disease, IC₅₀: Half-maximal inhibitory concentration

and observed a significant increase of the proestrus phase ($P < 0.001$) and a subsequent significant reduction in the metestrus ($P < 0.01$) and diestrus ($P < 0.05$).^[67] *Asparagus racemosus* also caused a significant decline in the frequency of uterine contraction and was found safe even at the limited dose of 5000 mg/kg.^[67] Panday *et al.* studied the effect of *Asparagus racemosus* Rhizome (*Satāwar*) on the Mammary Gland and Genital Organs of Pregnant Rats, and findings revealed a significant prominence of the mammary glands, increased weight of the uterine horns ($P < 0.001$), which shows an estrogenic effect of *Satāwar* on the female mammary gland and genital organs.^[68]

Clinical Studies: [Table 2]

Satāwar is used in various gynecological diseases in the Indian system of medicine, and only a few clinical studies have been done to generate data about the efficacy of *Asparagus racemosus* in the management of PCOS. In an open-label randomized comparative clinical trial to evaluate the efficacy of satapushpa-*shatavari* powdered drug with satapushpa-*shatavarigrita* for the management of polycystic ovary syndrome, carried out by Kumarapeli *et al.*, it was reported that satapushpa-*shatavari* encouraged the healthy ovarian follicle, controlled the menstrual cycle, and significantly improved ($P < 0.05$) endometrial thickness, hirsutism, and body weight in the management of PCOS.^[69] Majeedi *et al.* reported in another randomized controlled clinical trial that *Asparagus racemosus* is effective in stimulating follicular growth and ovulation in anovulatory *Uqr* (infertility) in PCOS patients, as *Satāwar* possesses properties such as ovulation-inducing and aphrodisiac, and is known to contain phytohormones (steroidal saponins and glycosides).^[70]

Discussion

The findings of this review support that *Asparagus racemosus* (*Satāwar*) possesses a wide spectrum of therapeutic actions that can be effectively utilized in the management of polycystic ovary syndrome (PCOS). Evidence from classical Unani literature and modern pharmacological research suggests that the drug acts through multiple mechanisms, targeting both the endocrine and metabolic dysfunctions that underlie the disorder.

In the Unani system of medicine, the pathogenesis of PCOS can be correlated with *Su'-i-Mizāj Bārid* (cold morbid temperament) and predominance of *Balghamī* (phlegmatic) humor, leading to disturbances in hepatic and reproductive functions^[17-20]. The resultant accumulation of abnormal *Balgham* interferes with ovarian function, producing symptoms analogous to amenorrhea, infertility, obesity, and hirsutism. The therapeutic strategy in Unani medicine, therefore, aims to correct humoral imbalance, restore normal *Mizāj*, and strengthen reproductive vitality through drugs possessing *Muqawwī-i-Raḥim*, *Mudir-i-Hayd*, and *Muqawwī-i-Bāh* actions. *Satāwar*, described as moderately

Table 2: Clinical studies on *Satāwar* (*Asparagus racemosus*) in polycystic ovary syndrome management

Title	Research design	Intervention	Control drug	Doses	Outcome measures	Number of patients	Interpretation
A randomized clinical trial to evaluate the efficacy of satapushpa- <i>shatavari</i> powdered drug with satapushpa- <i>shatavarigrita</i> for the management of PCOS ^[69] (2018)	An open-label randomised comparative clinical trial	Satapushpa and <i>Shatavari</i> in combination (oral intake and enema) Powder (seeds, roots)	Satapushpa and <i>Shatavari</i> in combination (only oral use) Satapushpa and <i>Shatavari</i> in combination (only enema) Satapushpa and <i>Shatavari</i> in combination (both oral and enema)	5 g t. d. s. with 10 mL of cow's ghee for (2 weeks) oral and enema	Ultrasound scan PCOS appearance of the ovary Volume of the ovary Endometrial thickness BW Hirsutism rating score	54 patients (18–42 years)	Reduction in volume of the ovary Significant improvement ($P < 0.05$) in endometrial thickness BW Hirsutism ratings score was significantly ($P < 0.05$) improved
Efficacy of <i>A. racemosus</i> (<i>Satāwar</i>) in stimulating follicular growth and ovulation in anovulatory infertility: A randomized controlled trial ^[70] (2016)	Clinical A randomized standard controlled study	<i>A. racemosus</i> (Root powder) Oral intake	Clomiphene	6 g twice daily from day 1–14 of the cycle for 2 consecutive cycles	Follicular growth and ovulation Conception	40 (Infertile women with PCOS [18–40 years of age])	<i>Satāwar</i> is significantly effective in stimulating follicular growth and ovulation (No significant difference when compared with clomiphene)

PCOS: Polycystic ovary syndrome, *A. racemosus*: *Asparagus racemosus*, BW: Body weight



Figure 1: *Satāwar* (*Asparagus racemosus*)

hot and moist in temperament, aligns perfectly with this approach and is traditionally employed as a uterine tonic, emmenagogue, galactagogue, and aphrodisiac.^[18,19,22]

Modern scientific studies strongly support these classical observations. Phytochemical research has identified steroidal saponins such as shatavarins (I–IV), sarsasapogenin, flavonoids (quercetin, rutin, hyperoside), and isoflavones that possess phytoestrogenic, antioxidant, and anti-inflammatory properties.^[26-29] These bioactive compounds work together to influence hormones by boosting follicular maturation, regulating gonadotropin levels, and enhancing insulin sensitivity. *In vitro* and *in silico* studies have shown that *A. racemosus* inhibits α -amylase, encourages glucose uptake, and interacts with insulin receptor substrates (IRS1 and IRS2), thereby reducing hyperglycemia and hyperandrogenism which are key features of PCOS.^[64]

The preclinical findings reviewed herein further substantiate these mechanisms. Animal studies have shown that *A. racemosus* stimulates the hypothalamic–pituitary–gonadal axis, increases serum levels of gonadotropins and ovarian hormones, and promotes folliculogenesis.^[65-67] Histological examination revealed proliferation in mammary and uterine tissues, indicating estrogenic activity.^[68] These findings are consistent with Unani concepts that emphasize revitalization of the reproductive system (*Taqwiyat-i-Rahim*) and promotion of natural ovulation (*Tawallud-i-Manī*).

Clinical evidence, although limited, also supports these observations. In a randomised comparative clinical trial, *Satāwar* administered with *Satapushpa* significantly improved ovarian morphology, endometrial thickness, and hirsutism scores in PCOS patients.^[69] Another study found *A. racemosus* to be effective in inducing follicular growth and ovulation in anovulatory infertility, with results comparable to clomiphene citrate but without its adverse effects.^[70] These findings highlight the potential of *Satāwar* as a safer and well-tolerated therapeutic alternative

in reproductive disorders associated with hormonal imbalance.

The therapeutic benefits of *Satāwar* extend beyond the reproductive axis. Its antioxidant and hepatoprotective properties help regulate hepatic metabolism and hormonal clearance, addressing one of the key pathophysiological contributors to PCOS. Moreover, its demulcent and nutritive properties support gastrointestinal health, which recent evidence links to gut microbiome balance and hormonal homeostasis in PCOS.^[60,61] This systemic mode of action reflects the Unani concept of holistic restoration of balance in *Akhlāt* (humors) and *A'zā'* (organs).

However, despite promising outcomes, the existing literature reveals some limitations. Most studies have small sample sizes, short intervention durations, and variations in extraction methods, making cross-comparison difficult. In addition, few trials have explored molecular pathways or long-term safety data. Hence, there is a need for rigorously designed, multicentric clinical trials and molecular-level studies to elucidate the pharmacodynamic pathways and establish standardized formulations. Both classical Unani understanding and contemporary scientific evidence converge to recognize *Satāwar* (*Asparagus racemosus*) as a potential multi-targeted botanical agent for PCOS management. It addresses hormonal dysregulation, metabolic imbalance, and inflammatory stress, while simultaneously restoring reproductive health. The integration of such validated Unani Medicine into modern reproductive care could provide a safer, holistic, and evidence-based approach to the long-term management of PCOS.

Conclusion

Among females, polycystic ovarian syndrome (PCOS) is one of the most prevalent reproductive illnesses. There is a dearth of effective treatment options for PCOS despite the use of many medications to treat its various symptoms. In recent years, there has been an increase in interest towards herbal medicines. So, there is an immediate need for more clinical studies to prove the efficacy of Unani medicines in the management of reproductive disorders. It is necessary to revisit this ancient science and evaluate the effectiveness and safety of the Unani system of Medicine in the management of PCOS. This calls for further exploration of the potential of *Satāwar* in ameliorating this syndrome. *Asparagus racemosus* possesses a complex phytochemical profile, with steroidal saponins, flavonoids, and other bioactive compounds contributing to its diverse therapeutic effects, and their pertinence in PCOS to be further explored. While these are some of the likely bioactive constituents of *Satāwar* that could contribute to its effects on PCOS, it is essential to note that more research is needed to fully understand the mechanisms of action and efficacy of *Satāwar* in managing PCOS.

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Conflicts of interest

There are no conflicts of interest.

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Sū'-i-Mizāj Jigar Ḥār: A Comprehensive Exploration of Its Conceptual Framework, Systemic Manifestations, and Management in Unani Medicine

Abstract

The concept of *Mizāj* (temperament) is a distinctive feature of the Unani System of Medicine, setting it apart from all other traditional medical systems. Just as individuals possess a unique *Mizāj*, each organ within the human body is characterized by a specific temperament that enables it to carry out its normal physiological functions. Any alteration in this temperament may result in functional disturbances, termed as *Sū'-i-Mizāj* (impaired temperament). The vegetative faculty, which governs all vital metabolic processes, is central to the body's functionality, with the liver serving as its principal organ. The temperament of the liver is classified as *Ḥār Raṭb* (hot and moist), and its primary function is to synthesize *Akhlāṭ* (humors), which are essential for the nourishment and restoration of bodily organs. Consequently, any disruption in the liver's normal temperament due to various factors can lead to an imbalance in the production of humors, thereby impairing the process of nourishment and potentially giving rise to a range of diseases. This paper aims to elucidate *Sū'-i-Mizāj Ḥār Jigar*, i.e., a pathological state characterized by an increase in *Harārat* (heat), with or without the involvement of matter, and its effect on the functioning of various bodily organs and its management. The study draws upon primary sources, including classical Unani texts, as well as secondary data from published and online resources.

Keywords: Heat, humor, liver, Sū'-i-Mizāj, temperament, Unani medicine

Introduction

The Unani System of Medicine encompasses doctrines that address both the composition and existence of the human body, which focuses on health as a state governed by the equilibrium of *Umūr Ṭabī'īyya* – , the seven fundamental principles. These are: (1) *Arkān* (basic constituents), (2) *Mizāj* (temperament), (3) *Akhlāṭ* (humors), (4) *A'dā'* (organs), (5) *Arwāḥ* (pneuma), (6) *Quwā* (faculties), and (7) *Af'āl* (functions).^[1,2]

According to Unani philosophy, *Arkān* are regarded as the four fundamental elements essential for the origin of life and the formation of the cosmos. Consequently, every compound in existence, including the human body, is constituted from these four elements: Fire, Air, Water, and Earth.^[3,4] *Mizāj* refers to the quality derived from the intermixture of these *Arkān*, both in terms of quantity and quality, in a specific proportion. The term *Mizāj* originates from Arabic, and its English equivalent is "Temperament," derived from the Latin

word *tempero*, meaning "to mix." According to the Unani System of Medicine, every organism or compound is endowed with a specific temperament, which determines its properties and functions. Similarly, the functions of bodily organs are dependent on their temperament and structural integrity. However, these functions are carried out by different faculties. When the temperament and structure of organs remain balanced, the faculties remain intact, ensuring proper functioning. Conversely, any disturbance in temperament (*Sū'-i-Mizāj*) or structural composition (*Sū'-i-Tarkīb*) disrupts the faculties of the organs, leading to altered or impaired functions.^[1,5] *Sū'-i-Mizāj* (impaired temperament) refers to the pathological deviation of an organ's natural temperament, either qualitatively (e.g., abnormal heat, cold, dryness, or wetness) or quantitatively (excess), resulting in functional derangement. Classical Unani scholars emphasize that impaired temperament is often the earliest stage of disease manifestation, preceding structural damage, and if left untreated, it can progress to *Sū'-i-Tarkīb* (alteration of structure) and eventual organic pathology.^[4,6]

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Central to the maintenance of normal temperament is the liver (*Kabid*), which is regarded as the principal organ for the production and refinement of *Akhlāt* (humors). The liver synthesizes and regulates the balance of humors: *Dam* (blood), *Balgham* (phlegm), *Şafırā'* (yellow bile), and *Sawdā'* (black bile), whose equilibrium is essential for sustaining organ temperament and, consequently, the integrity of their faculties. Any dysfunction of the liver or aberration in humoral production disrupts this balance, predisposing organs to impaired temperament and functional decline.^[1,7]

Role of liver as a vital organ of the nutritive faculty (*Quwwat Ghādhīya*)

In the Unani System of Medicine, the liver is regarded as the vital organ (*Ra'īs Muṭlaq*) of the Nutritive Faculty (*Quwwat Ghādhīya*) because it plays a central role in metabolism and nourishment. It is the primary site where ingested food undergoes successive stages of transformation to yield *Akhlāt* (humors), the vital nutritive substances that sustain bodily functions and temperamental balance. The liver is often referred to as the “Kitchen (*Maṭbakh*)” of the body, a metaphor coined in classical texts, because it processes food into its final nutritive form. Ibn Rushd (1987) emphasized that the liver’s metabolic activity directly determines the quantity and quality of humors produced, which are responsible for replenishment, tissue repair, and maintaining the equilibrium of temperament (*Mizāj*) across all organs.^[1,3,7]

Hippocrates (*Buqrāt*) also underscored its importance by stating that “*most of our life is dependent on the liver,*” highlighting its indispensable role in sustaining vitality. Any disturbance in liver function leads to the production of defective humors (*Akhlāt Fāsida*). Thus, the liver not only serves as the hub of nutritive processes but also indirectly influences the faculties (*Quwā*) of other organs by preserving their natural temperament through the continuous supply of balanced humors.”^[1] *Jalinoos* has called the liver as *Ra'īs Muṭlaq* (vital organ) of nutritive faculty (*Quwwat Ghadhiya*), i.e., the faculty responsible for Nutrition and replenishment. He compared this system to the solar system and said that the liver occupies the same position in the body as the sun among the stars. The liver is a center of vegetative faculty (*Quwwat Tabī'īyya*) and its subservient faculties that help in providing nourishment to all body organs through blood (humors).^[8]

Metabolism occurs in every part of the body organs in order to replenish the material that has been lost due to the continuous dissolution process (*Badl Mā Yatahallal*) in the body, which occurs due to ongoing biological processes. All this is governed by the Nutritive faculty and the liver, i.e., the main organ for metabolism, plays a vital role in this process.^[9,10] The liver is a primary organ for the production of Akhlāt (Humors). These humors are those

body fluids that provide nourishment to the body and replenish the lost material. After the formation of Humors, they are transported to each organ through vessels (*Urooq*) and a series of transformations occur in these fluids in terms of colour, consistency and Temperament so that these fluids resemble the organ to be nourished. These changes are necessary because the replenishing material should be identical to the dissipated material. All this process occurs under the supervision of *Tabiyat* with the help of *Quwwat Ghadhiya*. Therefore proper functioning of Nutritive faculty is an essential for proper nourishment. Since *quwwat Ghadiya* is present mainly in the liver, the maintenance of normal temperament of liver is of crucial importance.

***Sū'-i-Mizāj Jigar* (impaired temperament of liver)**

Different organs of the body are provided with different types of temperament as per their functional requirements. Hence, every organ has a distinctive temperament which is essential for its normal structure and function and is known as *Mizāj Mu'tadil Ṭibbī*, for example, the normal temperament of the liver is hot and wet (*Ḥārr Raṭb*); lungs are hot and dry (*Ḥārr Yābis*); bone is cold and dry (*Bārid Yābis*); brain is cold and wet (*Bārid Raṭb*), etc. These organs perform their functions normally only when their specific temperament remains within normal range/equilibrium.^[7,11]

Likewise, when the temperament of the liver is normal (hot and moist), it synthesizes normal humors in terms of both quality and quantity. The liver produces four types of humors, each serving to replenish specific organs according to their unique temperaments. For example, Sanguine humor replenishes muscle, liver, heart and other organs of hot and moist temperament, phlegmatic humor provides replenishment to brain, nerves, cartilage and other organs of cold and wet temperament because of the similar temperamental qualities. Likewise, bilious and melancholic humors nourish hot and dry and cold and dry organs, respectively. Thus, these four humors become the substitutes of the dissolved matter from the organs, as humors have the potential to transform into the dissolved part of the organ and hence provide replenishment.^[1] However, any deviation in the liver’s temperament from its optimal range disrupts its functions, leading to the production of abnormal humors, either in terms of quality or quantity.^[10] This compromise in humor production affects the nourishment and sustenance of bodily organs, potentially resulting in various diseases accompanied by distinct signs and symptoms. Such a pathological alteration in the liver’s temperament is referred to as *Sū'-i-Mizāj Jigar* (impaired temperament of the liver). *Sū'-i-Mizāj Jigar* may be *Sāda* (simple morbid temperament) or *Māddī* (morbid temperament associated with substance).^[4,7]

The temperament of the liver is deranged when one of the *kayfiyat Arba'a* (four basic qualities), i.e., *Ḥārr* (hot),

Bārid (cold), *Yābis* (dry), *Raṭb* (moist), and sometimes a combination of them, exceeds beyond their normal limits. Derangement of the liver is of the following types:

- *Sū'-i-Mizāj Ḥārr Jigar*
- *Sū'-i-Mizāj Bārid jigar*
- *Sū'-i-Mizāj Raṭb jigar*
- *Sū'-i-Mizāj Yābis jigar*^[3,12]

***Sū'-i-Mizāj Ḥārr Jigar* (morbid hot temperament of liver)**

When the temperament of the liver is altered due to an increase in its *Ḥarārat* (heat), it leads to abnormality in its functions known as *Sū'-i-Mizāj Ḥārr Jigar*.^[13] *Ahmad Bin Mohammad Tabari* while discussing liver diseases, has described 10 causes for weakness of the liver, among which one is the *Sū'-i-Mizāj Ḥārr Jigar*, and also mentioned *Sū'-i-Mizāj Ḥārr Jigar* as the most common type among the other four types because it is associated with *Ḥarārat*, which mainly interferes with the normal temperament of the liver.^[1,8]

Increase in *Ḥarārat* may occur without or with involvement of matter known as *Sū'-i-Mizāj Ḥārr Jigar sāda* or *Sū'-i-Mizāj Ḥārr Jigar Māddī*, respectively.^[4,11] This can happen primarily due to any disease of the liver or as a secondary cause due to any disease of neighboring organ.^[14] When the temperament of the Liver changes due to mild-to-moderate abnormal *Ḥarārat* (heat), i.e., *Sū'-i-Mizāj Ḥārr Jigar*, synthesis of *Khilt-i-Ṣafrā'* (bilious humor) increases abnormally because of the same temperamental inclination which results in the formation of different types of *Ṣafrā' Ghayr Ṭabī'ī* (abnormal bilious humor).^[11,13] Hence, the resulting abnormal bile produced is either hotter and drier than the normal bile present in the body or more in quantity or a combination of both. Due to an increase in quantity, the gallbladder exceeds its normal capacity to store bile, due to which there is an abundance of abnormal bile present in the blood. As a result, organs continue to receive their nutrition from *Ṣafrā' Ghayr Ṭabī'ī* and they develop *Sū'-i-Mizāj Ṣafrāwi*, causing *Amrād-i-Ṣafrāwiyya*, i.e., diseases of abnormal bile. Ibn Rushd describes *Amrād-i-Ṣafrāwiyya* under the heading of hot and dry diseases.^[4,7,15] When the temperament of the liver changes due to the presence of the extreme *Ḥarārat*, i.e., abnormal and excess hotness, it leads to the burning (*Ihtiraq*/combustion) of these humors, and as a result, the temperament of the humors will get converted into melancholic temperament (*sawdawi Mizaj*). This excess heat also causes the conversion of phlegmatic humor into black bile that is known as *Sawdā' Balghamī*, Sanguineous humor to sanguineous black bile or *Sawdā' Damawī*, Yellow bile into *Sawdā' Ṣafrāwī*, and Black bile converts into very thick and sticky humor known as *Sawdā' Sawdāwī*, which are abnormal (*Ihtiraque*/burnt) in nature.^[2,16,17]

Causes of *Sū'-i-Mizāj Ḥārr Jigar*:

Excessive heat production due to over consumption of *Ḥārr Ghidhā* (diet) as well as *Ḥārr Dawa* (hot temperament medications).^[7]

Obstruction between the liver and gallbladder.^[18,19]

Increased *Ḥarārat* in the heart.^[19,20]

Excessive consumption of alcohol and other alcoholic beverages.^[4]

Vigorous physical and mental exercises.^[13,20]

Occupations which produce excessive heat within the body or externally.^[3,11]

Sometimes, the production of *Ṣafrā'* and the temperament of the liver is normal, but due to the obstruction of the duct between the liver and gallbladder (common hepatic duct) or the common bile duct, the amount of *Ṣafrā'* increases in the blood and causes *Amrād-i-Ṣafrāwi* at different levels.^[7,11,13,21,22]

All these causes mentioned above, described by various scholars, are responsible for *Sū'-i-Mizāj Ḥārr Jigar*, and factors like intake of improper quantity and quality of food in inappropriate sequence and inaccurate time lead to production of *Ghayr Ṭabī'ī Akhlāṭ* (abnormal humors), resulting in *Sū'-i-Mizāj* of liver and other organs as well, resulting in a variety of diseases in different systems, for example, *Yarqān* (Jaundice), *Dharab-o-Khilfa* (Malabsorption syndrome), *Ishāl Damawī* (bloody diarrhea), etc.^[4,23]

Sign and symptoms of *Sū'-i-Mizāj Ḥārr Jigar*

Dry nostrils, dry lips, dry mouth, rough tongue, bitter taste, excessive thirst, nausea, and bilious vomiting.^[13,19]

Hiccup, hyperacidity, loss of appetite, indigestion, dull ache in the hepatic region, heaviness at the right hypochondrium, thus unable to sleep on the right side^[2,3,13]

Irregularity in bowel habits, diarrhea, abdominal pain, and painful defecation^[20]

Heat intolerance, increased heartbeat, rapid pulse^[13]

Malaise, fever, weakness, and weight loss^[12,13]

Burning and tingling sensation, feeling of tactile sensation in the body^[21]

Dull face with pallor of the conjunctiva, yellowish skin, itching^[12,13]

Urine with a thin consistency and yellowish in color, and foul-smelling urine, dry and foul-smelling stool^[4]

Presence of hair on the abdomen, enlargement in the liver and spleen^[7]

Sees fire, yellow objects in dream, excessive psychological manifestations such as extreme anger, emotions, boldness, anxiety, worry, carelessness, lack of sleep^[3,4,7,12,14,21,24]

Systemic manifestations of *Sū'-i-Mizāj Hārr Jigar*

Whenever the temperament of liver is altered either within a mild-to-moderate range (in terms of *Harārat*) or toward an extreme state of *Harārat*, both the conditions lead to the formation of excess and abnormal synthesis of bilious humor and abnormal black bile (*Sawdā' Ghayr Ṭabī'ī*) respectively.^[4,17] This aberrant bile circulates through the blood vessels, spreads to various organ systems and triggers a range of pathological conditions and diseases, which can be summarized as follows:

Systemic Manifestations of *Sū'-i-Mizāj Hārr Jigar*:

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1. Effects on *Nizām-i A'sāb-o-Dimāgh* (central nervous system): The central nervous system is a system related to sensory and motor functions of the body. External sensory organs, sensory and motor nerves, internal sensory bodies, and the spinal cord are the related components of this system.^[25,26] The body humors formed in the Liver are the source of nutrition and replenishment for the organs of *Nizām-i A'sāb-o-Dimāgh*. If the proportion of humors in terms of quantity and quality is normal, the central nervous system works efficiently without any disturbance because of the proper nourishment, but abnormal humors lead to certain pathological conditions. Different types of abnormal humors formed due to *Sū'-i-Mizāj Hārr Jigar*; responsible for different pathological conditions or diseases in the central nervous system, are classified in Table 1.

Table 1: Diseases of central nervous system caused due to *Sū'-i-Mizāj Hārr Jigar*

Type of Humor	Disease/pathological condition
<i>Ṣafrā' Ghayr Ṭabī'ī</i> (abnormal yellow bile)	<i>Sarsām Ṣafrāwī</i> (bilious meningitis), <i>Ikhtilāf al-'Aql</i> (Mental derangement), <i>Sahar Yābis</i> (insomnia), <i>Ṣar' Dimāghī Ṣafrāwī</i> (bilious epilepsy), <i>Abūblaṣiyā</i> (apoplexy), <i>iktināq al-riḥīm</i> (hysteria), <i>Nisyān</i> (Amnesia) ^[12,19,27]
<i>Sawdā' Damawī</i> (Sanguineous black bile)	<i>Mālankhūliyā Marāqī</i> (melancholia due to involvement of peritoneum), <i>kabūs</i> (nightmare) etc. ^[19,27]
<i>Sawdā' Ṣafrāwī</i> (Bilious black bile)	<i>Junūn Saba'ī</i> (Mania), <i>Hadhayān</i> (delirium), <i>Dā' al-Kalb</i> (cynanthropy), <i>Quṭrub</i> (melancholia with intentional loneliness) ^[11,13,19,21,27]
<i>Sawdā' Sawdāwī</i> (melancholic black bile)	<i>Mālankhūliyā</i> (Melancholia) ^[19,21,23,27]

2. Effects on *Nizām-i-Haḍm* (digestive system): The digestive system of the body consists of, mouth, esophagus, stomach, intestines, liver, and spleen. Hence, the main purpose of these organs is to assist the liver in the synthesis of humors by the transformation of nutrients for nutritional and replenishment purposes for all body parts. The organs of the digestive system execute their assigned functions through the nutritive faculty and other subfaculties. Any weakness or abnormality in these faculties leads to functional disturbance. A specific Temperament (*Mizāj*) is also essential to accomplish these functions. Any disturbance in temperament may lead to the weakness of the faculty. Diseases of Digestive System due to *Sū'-i-Mizāj Hārr Jigar* are mentioned in Table 2.^[17]

Table 2: Diseases of digestive system caused due to *Sū'-i-Mizāj Hārr Jigar*^[28]

Type of Humor	Disease/pathological condition
<i>Ṣafrā' Ghayr Ṭabī'ī</i> (abnormal yellow bile)	<i>Waram wa Buthur al-Mari Ṣafrāwī</i> (Bilious Esophagitis), <i>Qurūḥ al-Marī</i> (oesophageal ulcer), <i>Dukhāni Dakar</i> (GERD), <i>Waram-i-Mi'da Ṣafrāwī</i> (bilious gastritis), <i>Qurūḥ-i-Mi'da</i> (gastric ulcers), <i>Al- Tahawwu'</i> (retching), <i>Ishal Ṣafrāwī</i> (bilious diarrhoea), <i>Waram al-Kabid al-Ṣafrāwī/Waram-i-Jigar Ṣafrāwī</i> (bilious inflammation of liver), <i>Ishāl Kabidī Ṣafrāwī</i> (bilious diarrhoea due to involvement of liver), <i>Yarqān Aṣfar</i> (icterus/ jaundice), <i>Zalq al-Am'a</i> (lienteric diarrhoea), <i>Warm Kabid falgmoonī</i> , <i>Dharab-o-Khilfa</i> (sprue), <i>Waram al-Kabid al-Ṣafrāwī/Waram-i-Jigar Ṣafrāwī</i> (bilious inflammation of liver), <i>Istisqā'</i> (dropsy), <i>Ishāl Sahjī</i> (diarrhoea due to abrasion of intestine), <i>Qūlanj Ṣafrāwī</i> (bilious large intestinal colic) etc. ^[8,12,23,27]
<i>Sawdā' Ṣafrāwī</i> (Bilious black bile)	<i>Qurūḥ-i-Mi'da</i> (Gastric Ulcers), <i>Yarqān Aswad</i> (blackish discoloration of the skin), <i>Su'-i Mizāj Ṣafrāwī Mi'da</i> (Bilious Dystemperament of humor), <i>Dharab-o-Khilfa</i> (sprue) <i>Dhūsantāriyā/Ishāl al-Dam</i> (bloody diarrhoea), <i>Qūlanj Ṣafrāwī</i> (bilious large intestinal colic) ^[13,15,27]
<i>Sawdā' Sawdāwī</i> (melancholic black bile)	<i>Waram-i-Mi'da Sawdāwī</i> (melancholic gastritis), <i>Yarqān Aswad</i> (blackish discoloration of the skin), <i>Waram al-Kabid Saratani</i> (Hepatic Carcinoma), <i>Buṭlān al-Shahwa/Suqūṭ al-Shahwa/Dhahāb al-Shahwa</i> (anorexia), <i>Qarha wa Buthur al-Mi'da</i> (Gastric Ulcers), <i>Fasād al-Haḍm/Sū' al-Haḍm</i> (dyspepsia) ^[13,19,27]
Other diseases	<i>Zahūr-'Illa al-Dajāja/ Pechis</i> (dysentery), <i>Dhūsantāriyā Mi'wī</i> (bloody diarrhoea of intestinal origin), <i>Yarqān Suddī</i> (obstructive jaundice), <i>Yaraqan atfaal</i> (Neonatal jaundice), <i>Jū' al-Kalb/Al-Shahwa al-Kalbiyya</i> (voracious appetite), <i>Sudab al-Kabid</i> (obstructions of liver), <i>Waram-o-Salaba-al-Tihal</i> (Spleenomegaly), <i>Bawāsīr</i> (haemorrhoid), <i>Istisqā' Ziqqī</i> (ascites), <i>Ḥaṣā al-Kabid/Ḥaṣāt-i-Jigar</i> (hepatic calculi), <i>Sū' al-Qinya</i> (mild oedema with hepatic insufficiency), <i>Ishāl</i> (diarrhoea), <i>Ishaali damwi</i> (sanguineous diarrhoea) ^[4,12,13,27]

Table 3: Diseases of cardiovascular system caused due to *Sū'-i-Mizāj Hārr Jigar*^[28]

Type of humor	Disease/pathological condition
<i>Ṣafrā' Ghayr Ṭabī'ī</i> (abnormal yellow bile)	<i>Waram-i-Ghishā'-i-Qalb</i> (pericarditis), <i>Sū'-i-Mizāj Hārr Qalb</i> (Hot dystemperament of heart), <i>Khafaqān</i> (palpitation), <i>Taqashshur al-Qalb</i> (sensation of scratching of heart), <i>Warm azlat qalb haad</i> (Cardiac hypertrophy), <i>Azmul qalb</i> (Cardiomegaly) ^[2,13,28]
<i>Sawdā'</i> <i>Sawdāwī</i> (melancholic black bile)	<i>Sū'-i-Mizāj Sawda</i> of heart, <i>Ḍagḥ al-Qalb</i> (sensation of squeezing of the heart), <i>Illat Dukhāniyya/Dukhāniyat-i-Qalb</i> (sensation of upward pulling of heart), <i>Imtilā'-i-Ghilāf-i-Qalb</i> (pericardial effusion/pericardial) etc. ^[2,13,28]

Table 4: Diseases of reproductive system caused due to *Sū'-i-Mizāj Hārr Jigar*^[28]

Type of humor	Disease/pathological condition
<i>Ṣafrā' Ghayr Ṭabī'ī</i> (abnormal yellow bile)	<i>Sū'-i-Mizāj Hārr Ṣafrāwī Rahm</i> (Hot bilious dystemperament of uterus), <i>Waram al rahm Ṣafrāwī</i> (Bilious Endometritis), <i>Iḥtibās al-Ṭamth</i> (amenorrhoea), <i>Kathrat-i-Hayḍ</i> (polymenorrhoea), <i>Sayalān al-Raḥim</i> (leucorrhoea), <i>Ḥikka al-Raḥim</i> (pruritus uteri) ^[3,13,28]
<i>Sawdā'</i> <i>Sawdāwī</i> (melancholic black bile)	<i>Sū'-i-Mizāj haar Sawdā'wi rahm</i> (Melancholic dystemperament of uterus), <i>Waram al-Rahm Sawdāwī</i> (Melancholic Endometritis), <i>Sarāṭān al-Raḥim</i> (uterine carcinoma), <i>Qurūḥ al-Raḥim Sawdāwī</i> (uterine ulcers) <i>Ḥikka al-Raḥim</i> (pruritus uteri), <i>Kathrat-i-Hayḍ</i> (polymenorrhoea) ^[4,27,29]

In *Sū'-i-Mizāj Hārr Jigar*, the *Harārat* of stomach and liver increases abnormally, which is called *Harārat Ghariba* (morbid heat). Hence, *Harārat Ghariba* alters the temperament and causes weakening of subfaculties of digestive organs, i.e., *Quwwat Jādhiba* (absorptive faculty), *Quwwat Māsika* (Retentive faculty), *Quwwat Hādima* (digestive faculty) and *Quwwat Dafī'a* (expulsive faculty). Weakening of these faculties is responsible for various diseases of the gastrointestinal tract listed below:^[1,14,15]

3. Effects on *Nizām Qalb wa 'Urūqiyya* (cardiovascular system)

The heart is the most vital organ of our body as it produces and supplies vital pneuma and vital faculty. The Heart helps in supplying nutrition through the blood to all parts of the body. *Sū'-i-Mizāj Hārr Jigar* can affect the heart because the abnormal and inappropriate nutritive and replenishing material reaches the heart in the form of abnormal humors. Diseases of Cardiovascular System due to *Sū'-i-Mizāj Hārr Jigar* are mentioned in Table 3.

4. Effects on *Nizām-i-Tānāsul* (Reproductive system)

The reproductive system is equally important for the continuation of the human species. There are several organs related to reproduction, for example vagina, cervix, uterus, ovaries, and uterine tubes in females, while the penis, prostate, vas deferens, epididymis,

and testes in males. Like all other systems, abnormal humors may produce numerous pathological conditions in these organs as mentioned in Table 4.

5. Effects on *Nizām Jild-o-Taz'niyāt* (Skin and Cosmetology):

Morbid or abnormal humors also affect the integumentary system and produce various skin disorders. Sometimes, the morbid matter, like abnormal *Ṣafrā* and *sawda* get accumulated beneath the layers of skin and produces a variety of skin diseases. Sometimes, the *Ṭabī'iyat* excretes the wastes, i.e., *Akhlāt Ghalīdha* toward the skin for the expulsion, but due to the weakness and some other causes, the skin is unable to excrete that morbid matter properly, which accumulates and produces diseased conditions.^[13,19,20] The nature of disease, sign and symptom, severity and type of lesion depends upon the nature of abnormal humors formed in the diseased liver. As per Unani literature, there are several diseases produced as a systemic manifestation from *Sū'-i-Mizāj Hārr Jigar*, mentioned in Table 5.

Methodology

The literary material in the form of statements and descriptions related to the topic was meticulously reviewed and gathered from various sources. Significant time was dedicated to examining diverse manuscripts, their translations, books, and other related publications. Online web portals and different online search engines such as PubMed, Google Scholar, and many more platforms, were also surveyed to collect the relevant references.

The literary material related to *Sū'-i-Mizāj Hār Jigar* and its systemic effects was collected from three sources, which are as follows:

- 1) Classical literature, manuscripts and their translations are used as the primary data sources, i.e., *Al-Qanoon-Fit-Tib*, *Zakhira Khawar-azam Shahi*, *Kamil-us-Sana'a*, *Kitab-ul-Kulliyat*, *Kulliyat-i Nafisi*, *Kulliyat-i-Qanoon*, *Al-Aqseer*, *Kitab-al-Taiseer*, *Kitabul-Mia*, *Kitabul-Mukhtarar-Fit-Tib*, *Al-Mualajat-ul-Buqratiya* and *Firdaus-ul-Hikmat*, etc
- 2) All other related literature in published and unpublished forms were surveyed as a secondary data collection
- 3) The third source of data collection was subject-specific, professional websites, for example, greekmedicine.net, imedpub.com, ncbi.nlm.nih.gov/books and other digital online citations.

Discussion

Each organ of the body possesses a specific *Mizaj* (temperament) which determines its structure, appearance and functionality. An organ performs its natural functions properly only when the temperament of that organ is *Mutadil* (equable). Any disturbance in their equability can alter the capacity of the organ and its normal functioning.

Table 5: Diseases of skin and hair caused due to *Sū'-i-Mizāj Hārr*^[28]

Type of humor	Disease/pathological condition
<i>Ṣafrā' Ghayr Ṭabī'ī</i> (abnormal yellow bile)	<i>Awram Ṣafrāwi</i> (bilious swelling), which includes; <i>Humra/Mashara</i> (Eryseplas), <i>Namla</i> (herpes zoster), <i>Hasba</i> (Small pox), <i>Jarab</i> (Scabies), <i>Sharā</i> (urticaria/ hives), <i>Buthūr Ṣafrāwi</i> (eruptions), <i>Jamra</i> (carbuncle), and <i>Ḥaṣaf/Buthūr Shawkiyya</i> (prickly heat), etc. ^[13,23,27]
<i>Sawdā'</i> <i>Sawdāwī</i> (Melancholic Black bile)	<i>Bahaq Aswad</i> (pityriasis nigra), <i>Baraṣ Aswad</i> (a type of ichthyosis), <i>Kalaf</i> (melasma), <i>Taqashshur al-Jild</i> (scaling with roughness of skin), <i>Qūbā</i> (Ringworm), <i>Khīlan</i> (Mole), <i>Namash</i> (naevus), <i>Tha'ālīl</i> (Warts), <i>Dā' al-Ḥayya</i> (alopecia with loss of a layer of skin), <i>Dā' al-Tha'lab</i> (alopecia areata), <i>Illa al-Nuama</i> (type of alopecia in which the skin of scalp resembles with the skin of ostrich with plucked feathers), <i>Intūhār al-Sha'r</i> (hairfall), <i>Tashaqquq al-Sha'r</i> (split end of hair) etc. ^[4,20,27]
Other diseases	Swellings and tumours which include: <i>Saqirūs</i> (Hard swelling), <i>Sal'at</i> (Tumours), <i>Saraṭān</i> (Carcinoma) and <i>Amrā-i-Umumi</i> , including <i>Judhām</i> (Leprosy), <i>Dawālī</i> (varicose veins), <i>Dā' al-Fīl</i> (elephantiasis/filariasis), <i>Hummā-al-Ṣafrāwi</i> (bilious fever), etc. ^[19,21,27]

The liver's normal temperament is classified as *Hārr-Raṭb* (hot and moist). However, when the liver's *Mizāj* deviates due to an increase in mild-to-moderate abnormal heat, it leads to the excessive and irregular synthesis of bilious humor, resulting in *Sū'-i-Mizāj Ṣafrāwi* (bilious imbalance), which manifests as various bilious diseases across different body organs and systems.^[17] In cases of extreme *Ḥarārat* (heat), abnormal humors or burnt (*ihṭirāqi*) black bile are produced, including *Sawdā-i-Balghami* (phlegmatic black bile), *Sawdā-i-Damvi* (sanguine black bile), *Sawdā-i-Ṣafrāwi* (bilious black bile), and *Sawdā-i-Sawdawi* (pure black bile). These abnormal humors, produced as a consequence of *Sū'-i-Mizāj Hārr Jigar* enter the bloodstream, circulate throughout the body and nourish the organs, which in turn causes disruption of the normal temperament as the nourishing fluid is itself has a deranged temperament. They affect various organ systems, including the *Nizām-i-A'ṣab wa Dimāgh* (central nervous system), *Nizām-i-Qalb wa Shiryān* (cardiovascular system), *Nizām-i-Mi'da, Am'ā wa Jigar* (gastrointestinal and hepatic systems), *Nizām-i-Tanāsuliyya* (reproductive system), and *Nizām-i-Jild wa Sha'ir* (integumentary system). This widespread impact leads to disorders within these systems.

This discussion highlights the need for a deeper understanding of the mechanisms underlying *Sū'-i-Mizāj Hārr Jigar* and its systemic implications. In light of the classical treatment approaches outlined for *Sū'-i-Mizāj Hārr Jigar*, this study underscores how Unani regimens comprising cooling agents, hepatic tonics, evacuative measures, and dietotherapy are systematically

directed toward re-establishing hepatic equilibrium. These interventions aim not only to reduce hepatic heat but also to restore humoral balance, thereby preventing downstream pathological sequelae. Integrating such therapeutic frameworks into contemporary research models may offer novel, multi-targeted strategies for managing liver-related disorders. These insights not only enhance the understanding of Unani principles but also open avenues for integrating traditional knowledge with modern medical practices to develop holistic treatment strategies.

Treatment of *Sū'-e-Mizāj-e-Jigar Hārr*

Regimental therapies (*Ilaj Bil Tadbeer*)

Topical applications (Cold Poultices):

- Apply poultices prepared from *Cucurbita maxima* Duchesne (gourd) pulp, cucumber extract mixed with barley flour or lentil flour, *Santalum album* L.(sandalwood), rose (*Rosa* spp.) petals, and *Portulaca oleracea* L.(purslane)
- Use Rose water, *Santalum album* L.(red and white sandalwood) paste, *Viola odorata* L.(*banafsha*), and chicory (*Cichorium intybus* L.) extract for hepatic cooling
- Massage the liver area with *Roghan-e-Gul* (rose oil) mixed with white wax, or apply a paste of *Sumbul-ut-Teeb* (*Valeriana jatamansi* Jones ex Roxb.), *saffron* (*Crocus sativus* L.), *Myrrh* (*Commiphora myrrha* (Nees) Engl.), and *Azkhār* (*Cymbopogon* spp.), for hepatic fortification^[13,20]

Dietotherapy (*Ilāj bil Ghidhā*)

- Avoid: Hot, sweet, viscous, and obstructive foods.
- Recommended:
- Vegetables: Chicory (*Cichorium intybus* L., *Kasni*), lettuce (*Lactuca sativa* L., *Khas*), and beet greens (likely *Beta vulgaris* L., *Bathua*)
- Legumes: *Vigna radiata* (L.) R. Wilczek (Moong dal, green gram), and lentils (e.g., *Lens culinaris* Medik.) prepared in vinegar
- Meat: Small birds (partridge, quail), young goat (1–2 years), small fish, and light meats cooked in sour decoctions^[13]
- Camel milk with medicated powders, cow's buttermilk, and yoghurt^[19]
- Fruits: Pomegranate (*Punica granatum* L.), apple (*Malus domestica* Borkh.), jujube (*Ziziphus jujuba* Mill.), slightly sweet melons (*Cucumis melo* L.), moderate grapes (*Vitis vinifera* L.), watermelon (*Citrullus lanatus* (Thunb.) Matsum. and Nakai), mulberry (*Morus* spp.), citron (*Citrus medica* L.), orange (*Citrus sinensis* (L.) Osbeck), lemon (*Citrus limon* (L.) Burm. f.), and quince (*Cydonia oblonga* Mill.).^[3,4]
- Medicinal syrups and rubs: *Rub-e-Seeb* (apple electuary), *Rub-e-Anār* (pomegranate electuary), *Rub-e-Turunj* (citron electuary).^[3,19]

1. Pharmacotherapy (*Ilaj Bil Dawa*)

a) Cooling and strengthening the liver

- Administer cooling agents such as *Sharbat Anār* (pomegranate syrup), *Sharbat Zar Mūshk*, *Sharbat Nīlūfar* (water lily syrup), and *Arq-e-Kasni* (chicory water).^[3]
- Provide *Mā' ush-Sha'ir* (barley water) for both hepatic tonification and cooling, as it also helps in washing out morbid humors
- *Aab-e-Imli* (tamarind water) sweetened with sugar, *Aab-e-Khurfa* (purslane water), and *Sharbat Anār* (sweet and sour pomegranate syrup) may also be given
- For persistent heat, combine *Arq-e-Kasni* and *Sikanjabeen* (oxymel) with *Qurs Tabāshīr* (bamboo silica tablet) or *Qurs Kāfūr* (camphor tablet).^[2,29]

b) Purgation (in case of *Sū'-i-Mizāj Māddī*)

- In *Humra Safrāwī* (bilious predominance), induce mild purgation with *Haleela Zard* (*Terminalia chebula* Retz.), *Amlatās* (*Cassia fistula* L.), and pomegranate juice (sweet and sour)^[3]
- In *Humra Damawī* (sanguine predominance), perform phlebotomy (*fasd*) from basilic or axillary veins, provided strength, age, and season permit^[13]
- Use *Joshanda-e-Haleela* with *Cassia fistula* pulp for evacuative therapy.^[12]

c) Compound formulations

- *Sufūf Barāye Harārat-e-Jigar: Rose petals, Tabāshīr* (bamboo silica), purslane seeds, white sandalwood (*Santalum album* L.), Chinese rhubarb (*Rheum palmatum* L.), fennel (*Foeniculum vulgare* Mill.), celery seeds (*Apium graveolens* L.), and camphor (*Cinnamomum camphora* (L.) J. Presl), administered with sugar.^[13,19]
- *Qurs Nusūr*: Contain purslane seed, pumpkin seed (*Cucurbita maxima* Duchesne), chicory seed (*Cichorium intybus* L.), rose, *Tabāshīr*, rhubarb (*Rheum palmatum* L.), sandalwood (*Santalum album* L.), and saffron (*Crocus sativus* L.).^[3,12]

2. Adjunctive measures

- For persistent heat with bile dominance, give *Haleela Zard* (*Terminalia chebula* Retz.) with *Mā' al-Lahm* (whey water) for mild purgation
- Use cold baths, light sour syrups, and purslane extract with *Sikanjabeen* (oxymel) as supportive measures^[13]
- Maintain avoidance of sweet, dense, and heat-producing diets unless digestion is strong enough to handle cooked dense meats in cooling extracts.^[3,4,29]

Conclusion

The temperament of the liver is crucial in maintaining the balance of humors and ensuring the proper functioning of various organ systems. Any deviation from its normal temperament, whether through mild, moderate, or extreme increases in *Harārat*, can lead to significant pathological changes, including the synthesis of abnormal humors and the development of systemic

disorders. In the Unani framework, the interconnected nature of organ systems underscores the critical importance of preserving the temperament of the liver to maintain overall health and prevent disease. The classical therapeutic framework for *Sū'-i-Mizāj Hārr Jigar*, emphasizing cooling regimens, phlebotomy, purgation, and dietetic regulation, demonstrates the depth of Unani hepatology in addressing hepatic hyperthermia and its systemic effects. If applied appropriately within modern clinical paradigms, these principles hold potential for developing complementary strategies that support hepatic function, mitigate abnormal humor production, and reduce associated disease burden.

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Conflicts of interest

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Physicochemical Standardization of *Maghz-e-Pambadana* (Kernel of *Gossypium herbaceum L.*)

Abstract

Background: Adulteration and substitution of herbal medicines pose a significant challenge to maintaining the authenticity and therapeutic effectiveness of herbal products. The quality of raw plant materials is greatly influenced by factors such as geographical origin, the stage of plant growth during collection, post-harvest processing and storage. To ensure standardization, several national and international pharmacopoeias—including the Indian Pharmacopoeia (IP), British Pharmacopoeia (BP), United States Pharmacopoeia (USP), Japanese Pharmacopoeia (JP) and the Pharmacopoeia of the Republic of China—provide detailed monographs and quality control guidelines for medicinal plants. Likewise, the Unani Pharmacopoeia of India (UPI) outlines specific standardized tests to safeguard quality and authenticity. **Objective:** To extract *Maghz-e-Pambadana* (*Gossypium herbaceum L.*) seeds and evaluate the extract using quality control parameters prescribed in the Unani Pharmacopoeia of India (Part I). **Methods:** Seeds of *Maghz-e-Pambadana* were subjected to extraction, followed by a series of quality control tests as per UPI guidelines. These included (1) morphological examination, (2) powder analysis with specific reagents, (3) determination of ash content, (4) extractive value, (5) loss on drying, and (6) thin-layer chromatography (TLC)/high-performance thin-layer chromatography (HPTLC). **Results:** The extract of *Maghz-e-Pambadana* complied with all pharmacopoeial standards. Morphological features, chemical characteristics, moisture content, and chromatographic profiles were consistent with authentic reference material, confirming its identity and purity. **Conclusion:** Pharmacopoeial quality control testing effectively ensures the authenticity of *Maghz-e-Pambadana* and helps prevent adulteration. Such standardization is essential for maintaining the safety, efficacy, and therapeutic reliability of Unani herbal formulations.

Keywords: *Gossypium Herbaceum L.*, *physicochemical*, *phytochemical*, *standardization*

Introduction

Maghz-e-Pambadāna (kernel of *Gossypium herbaceum L.*) belongs to the family *Malvaceae*. The plant is indigenous to India, Pakistan, USA, Middle East countries, Central Asia and Africa. Eastern physicians consider all parts of the *Gossypium herbaceum L.* plant to be hot and moist and usable as medicine. The plant has been in use from the ancient periods. In the Unani literature, it is described as *Musammin-i-Badan* (adipogenous), *Muqawwī-i-Badan* (Aphrodisiac), *Muwallid-i-Manī* (Spermatogenic), *Muwallid-i-Laban* (galactopoietic), *Bawl-Zulālī* (Albuminuria) and for *Taqwiyat-i-Kulya* (toning up of kidney), etc.^[1]

The World Health Organization (WHO) currently encourages, recommends, and

promotes traditional/herbal remedies in National Health care programme because such drugs are easily available at low cost, are comparatively safe and the people have faith in such remedies. The WHO has well-defined the standardization of herbal drugs as “the process involved in the physicochemical evaluation of crude drug covering aspects such as selection and handling of crude material, safety, efficacy and stability assessment.”^[2] Plant materials and herbal remedies derived from them represent a substantial promotion of the global drug market and in this respect adoption of internationally recognized guidelines for their quality assessment are necessary. The WHO Assembly in a number of resolutions emphasized the need to ensure the quality control of medicinal plant products by using modern techniques and applying suitable standards. Adulterations

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and substitution have become a major problem in the availability of standards relating to genuineness of drugs, skill hands, and cost factors, etc.^[3]

Several pharmacopoeia including Indian Pharmacopoeia, British Pharmacopoeia, Pharmacopoeia of Republic of China, Japanese Pharmacopoeia, and United States Pharmacopoeia do cover monographs and quality control tests for few of the medicinal plants used in those countries, but basically, these pharmacopoeias are designed to cater the chemical-based medicines and pharmaceutical necessities by giving their standards test methods, etc. The Unani medicine is the traditional system of medicine practised in South Asian countries such as India, Pakistan, Bangladesh, etc. It was originated by the Greek philosopher Hippocrates along with his associates. However, it was recognized in the era of Persian and Arab empires.^[1]

The quality of a vegetable product depends on the geographical origin, time, and stage of growth when collections has been done and postharvest handling. The raw material presently available to the industry is procured from more than one geographical region. In most cases, villagers or tribal residing in the vicinity of forest collected the material in their spare time. The plant is collected without paying attention to the stage of maturity, dried haphazardly and stored for long period under unsuitable conditions. The quality of crude drug, as such, is more often degraded. Therefore, the standardization of herbal drugs is required and it has a set of standards which has constant parameters with defined qualitative and quantitative values. These parameters are stated in The Unani Pharmacopoeia of India (Part I), are as follows: (1) Morphological characters, (2) powder analysis with different reagents, (3) ash content, (4) extractive value, (5) loss on drying, and (6) TLC or HPTLC.

Materials and Methods

Plant material

The dried kernels of seeds of *Maghz-e-Pambadāna* (*Gossypium herbaceum L.*) were purchased from M/S Mohammad Hussain and Ajmal Hussain, Khari Bawli, Delhi - 110 006. The identity of the purchased drug was established as kernel of the seed of *Gossypium herbaceum L.* by the scientist at National Institute of Science Communication and Information Resources, Dr. K. S. Krishnan Marg, Pusa Gate, New Delhi-110012.

Preparation and extract of *Maghz-e-Pambadāna* (*Gossypium herbaceum L.*)

The crushed dried kernels of the seeds of *Gossypium herbaceum L.* were extracted with aqueous methanol using Soxhlet's Apparatus (25 cycles). Methanol was recovered by distillation method under reduced pressure. The dark brown residue left after removal of the solvent was coded

as aqueous methanolic extract (AME). The yield of AME was 15.7% w/w with respect to starting material.

Physicochemical and phytochemical investigation

Morphological characteristics

In some cases, general appearance of the herb is similar to related species. Detailed study of the morphological characters can be helpful in differentiating them. The macroscopic characters of a drug include its visual appearance to the naked eye. It depends to a large extent on the part of the plant from which the drug is obtained. For each group, a particular systemic examination can be carried out. Size, color, odor, and taste are the important parts of morphology of a particular drug. Their characters were observed and recorded.^[4]

Loss on drying

The drug sample was taken in clean petri dish of known weight, and the petri dish was weighed along the drug sample and weighed of the drug was noted again. The drug containing petri dish was kept in the oven at 105°C for 2 h, and then, the weight was noted. Then again, the drug with petri dish was kept in oven at 105°C for next 2 h. Then, the weight was recorded. The process was repeated till constant weight was obtained.

pH of crude drug

- pH of 5% solution: 5 g of drug was weighed and dissolved in 100 mL of distilled water. The resulting solution/mixture was filtered and pH was measured with a standard glass electrode
- pH of 10% solution: The experiment was performed in the same manner as above taking 10 g of drug instead of 5 g.

Extractive values

Successive extractives: The dried and coarsely powdered material (20 g) was subjected to successive extraction in a Soxhlet's apparatus with different solvents like petroleum ether, chloroform, and alcohol. The extracts were evaporated to dryness and their constant extractive values were recorded.

Ash values

- Total ash: The coarsed drug (1 g) was incinerated in a silica crucible at a temperature not exceeding 450°C until free from carbon. It was then cooled and weighed to get the total ash content
- Acid insoluble ash: Ash was boiled with 25 mL dilute HCl (6N) for 5 min. The insoluble matter collected on an ash less filter paper, washed with hot water and ignited at a temperature not exceeding 450°C to a constant weight
- Water soluble ash: Ash is dissolved in distilled water and the insoluble part collected on an ashless filter paper and ignited at 450°C to constant weight. By subtracting the weight of insoluble part from that of the ash, the weight of soluble part of ash is obtained.

Fluorescence analysis

Powdered drug (40 mesh) was treated with different reagents and examined under UV light (255 and 366 nm). Different reagents shows different color of the drug.

Powdered drug reaction with different reagents

The powdered drug was treated with different reagents and the color shown by that treatment was noted.

Estimation of total phenolic content

Five gram drug was taken in 50 mL distilled water in 100 mL conical flask. The content were boiled for 5 min and filtered on filter paper. The filtrate was shaken with 20 mL petroleum ether in separating funnel to remove greasy matter. The aqueous solution was precipitated with 5 mL saturated lead acetate solution, digested for few minutes on water bath. The content was filtered, the residue was dried and then suspended in ethyl-alcohol, warmed on water bath. H₂S gas was passed through the precipitate containing alcohol which decomposed the precipitate and the content was filtered. The clear alcoholic solution was concentrated under reduced pressure. It was subjected to vacuum distillation three times after adding fresh quantity of alcohol each time, to get rid of all the H₂S gas. The residue was transferred to an already weighed petri dish with the help of alcohol. Then, the alcohol was evaporated on water bath and residue was dried at 105°C.

Phytochemical investigation

Tests for saponins

- Foam test: A 50 mg of the test residue was taken in a test tube and shaken vigorously with a 20 mg of sodium bicarbonate and water. It is a stable, characteristic honeycomb like froth was obtained, indicating the presence of saponins.

Tests for tannins

The test residue of each extract was taken separately in water, warmed, and filtered. Tests were carried out with the filtrate using following reagents.

- Ferric chloride reagent: A 5% w/v solution of ferric chloride in 90% alcohol was prepared. Few drops of this solution were added to a little of the above filtrate. Dark green or deep blue color was indicating the presence of tannins
- Lead acetate test: A 10% w/v solution of basic lead acetate in distilled water was added to the test filtrate. If precipitate is obtained, tannins are present

- Potassium dichromate test: If on addition of a solution of potassium dichromate in a test filtrate, dark colour is developed, tannins are present.

Tests for flavonoids (Shinoda test)

A small quantity to test residue was dissolved in 5 mL ethanol (95% v/v) and reacted with few drops of concentrated hydrochloric acid and 0.5 g of magnesium metal. The pink, crimson, or magenta color is developed within a minute or two, if flavonoids are present.

Tests for proteins

- Biuret test: A few mg of the residue was taken in water and 1 mL of 4% sodium hydroxide solution was added to it. A drop of 1% solution of copper sulphate followed this. Violet or pink color is formed if proteins are present
- Xanthoproteic test: A little residue was taken with 2 mL of water and 0.5 mL of concentrated nitric acid was added to it. Yellow color is obtained if proteins are present.

Results and Discussion

The standardization of the herbal material was done for identification. The morphological characters, loss on drying, extractive value, ash values, pH values, fluorescent analysis, powdered drug reaction with different reagents, estimation of total phenolic content, and phytochemical analysis were determined and depicted in below tables. (As depicted in Tables 1-7).

Morphological characteristics

- Tree: It is a small shrub, 60 cm to 2.5 m in height with rigid sparsely pilose stems and branches. The stem is glabrous or slightly pubescent. Stem is usually ascending, with vegetative branches^[5]
- Leaves: It has alternate, palmate-lobate, leaves with unevenly incised lobes. Twigs and leaves densely hairy, rather large, usually thick, rumped, about two-thirds cut into five lobes^[5]
- Flowers: The flowers are born on singly on along peduncle or emerge in groups of 2–3 from the leaf axles, enveloped in bracts which form an outer calyx. The true calyx is relatively undeveloped and forms a cup of 5 obtuse teeth. The corolla consists of 5 large, white or sometimes pink or yellowish petals fused at the base. The numerous stamens form a central column^[5]

Table 1: Percentage loss of *Maghz-e-Pambadāna* (Kernel of *Gossypium herbaceum L.*) on drying

Weight of drug (g)	Weight of empty petri dish (g)	Weight of empty petri dish (g) + weight of drug (g)	Weight of empty petri dish (g) + weight of drug (g) after drying	Drug (%)
2	43.92	45.92	45.82	5
2	43.92	45.92	45.82	5
2	43.92	45.92	45.82	5
Mean	43.92	45.92	45.82	5

Table 2: Extractive matter (%) of extract of *Maghz-e-Pambadāna* (Kernel of *Gossypium herbaceum* L.) on successive extraction

Extract	Weight of drug (g)	Weight of empty petri dish (g)	Weight of empty petri dish (g) + weight of extractive matter (g)	Weight of extractive matter (g)	Extractive matter (%)
Petroleum ether extract	100	48.96	84.07	35.11	35.11
Chloroform extract	100	46.49	59.82	13.33	13.33
Alcoholic extract	100	37.30	57.19	19.89	19.89
Water extract	100	23.78	28.87	5.09	5.09

Table 3: Ash value (%) of kernels of *Maghz-e-Pambadāna* (Kernel of *Gossypium herbaceum* L.)

Ash	Weight of crucible (g)	Weight of drug (g)	Weight of crucible + weight of drug (g)	Weight of crucible after ignition (g)	Weight of ash (mg)	Ash value (%)
Total ash	32.12	5	37.12	33.09	0.97	19.4
Acid insoluble ash	32.12	5	37.12	32.24	0.12	2.4
Water soluble ash	32.12	5	37.12	32.48	0.36	7.2
Water insoluble ash	32.12	5	37.12	32.33	0.21	4.2

Table 4: Fluorescent analysis of *Maghz-e-Pambadāna* (Kernel of *Gossypium herbaceum* L.)

Solvent	Ordinary light	UV light (254 nm)	UV light (366 nm)
Petroleum ether	Transparent	Colourless	Light green
Benzene	Transparent	Colourless	White
Acetone	Yellow	Light green	Green
Ethyl acetate	Transparent	Colourless	Straw coloured
Chloroform	Pink	Transparent	Light brown
Methanol	Transparent	Colourless	Light pink
Water	Purple	Transparent	Sky blue
Dilute HCl	Violet	Brown	Purple
Dilute HNO ₃	Orange	Reddish	Yellow
Dilute H ₂ SO ₄	Black	Light brown	Light black

UV: Ultraviolet

Table 5: Details of observation of drug reaction with different reagents

Treatment	Observation
Concentrated HCl	Dark blue
Concentrated HNO ₃	Yellow
Concentrated H ₂ SO ₄	Dark brown
Iodine solution	Iodine colour
Glacial acetic acid	Orange
Powder as such	Purple

- Fruit: The fruit is a capsule with 2–5 loculi, each of which contains a fluffy tuft of cotton wool in which the seeds rest.^[5]

Loss on drying [Table 1]

The percentage loss on drying is shown in Table 1.

pH of crude drug

At 10%, pH found to be 6.30 while at 5%, it is 6.24.

Extractive values have been mentioned in Table 2

The percentage extractive values with different solvents in presented in Table 2.

Ash value shown in Table 3

The different ash values of *Maghz-e-Pambadana* (Kernel of *Gossypium Herbaceum*) are shown in Table 3.

Fluorescent analysis has been depicted in Table 4

Fluorescence analysis with various solvents is presented in Table 4.

Powdered drug reaction with different reagents shown in Table 5 as well

Drug reaction with various reagents in presented in Table 5.

Estimation of total phenolic content shown in Table 6

Total phenolic content (%) is presented in Table 6.

Phytochemical investigations depicted in Table 7

The details of different phytochemical investigations are presented in Table 7.

The amounts of extracts obtained are revealing the approximate quantity of their chemical constituents. Water-soluble extract indicate water soluble constituents of herbal drug, such as tannins, sugars, mucilage, glycosides, etc., however, alcohol is an best solvent for extraction of numerous chemicals such as tannins, resins etc. The moisture content of the drug is analysed to prevent it from decomposition, either due to microbial contamination or chemical imbalance.

Ash value is indicative to check the purity of herbal drug.

Conclusion

Standardization of herbal drugs is essential to assure the authenticity, quality, and purity as well as potency. The

Table 6: Drug % estimation of total phenolic content

Weight of drug (g)	Weight of empty China dish (g)	Weight of empty China dish + weight of drug (g)	Total phenolic content (g)	Drug (%)
2	42.37	43.02	0.65	32.5
2	42.37	42.99	0.62	31
2	42.37	42.99	0.62	31
Mean	42.37	42.99	0.62	31

Table 7: Details of phytochemical investigations

Tests	Powdered drug
Test for saponins	
Foam test	Positive
Test for tannins	
Ferric chloride reagent	Positive
Lead acetate test	Positive
Potassium dichromate test	Negative
Test for flavonoids	
Shinoda test	Positive
Test for proteins	
Biuret test	Negative
Xanthoproteic test	Positive

methods cited above helps in distinguishing the adulterated or spurious drugs with the authenticated ones. Therefore, it can be concluded the drug, *Maghz-e-Pambadāna* was authenticated properly.

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Conflicts of interest

There are no conflicts of interest.

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Evaluation of Unani Decoctions in *Hazāz* (Pityriasis capitis) – A Randomized Comparative Clinical Trial

Abstract

Introduction: Pityriasis capitis also referred as dandruff/pityriasis is a common dermatological problem characterized by itchy erythematous, greasy scaling, and furfuraceous flakes over the scalp. In view of its high prevalence and limited treatment options, this study was intended to assess the efficacy of *Joshānda Afīmūn* with *Āb-i-Chuqandar* versus *Joshānda Khubāzī* among the cases of dandruff. **Materials and Methods:** This study was a randomized comparative trial with 17 subjects in the test group and 18 in the control group. Both the groups received *Joshānda Afīmūn* 15 g orally twice a day. In addition, in the test group, *Āb-i-Chuqandar* mixed with *Borah Armanī*, and in the control group, *Joshānda Khubāzī* was given for hair wash twice in a week; similarly, both the groups were treated for 21 days. Assessment of the efficacy was made through scales on scalp, itching of scalp, Wood's lamp finding, Adherent Scalp Flaking Score, and photographs of the affected area. **Results:** The test formulation showed a significant improvement in the reduction of scales of scalp and itching of scalp ($P < 0.001$) on intragroup analysis, whereas there was no significant difference on intergroup analysis. **Conclusion:** These research findings support that orally *Joshānda Afīmūn* with local application of *Āb-i-Chuqandar* mixed with *Borah Armanī* is effective in reducing the symptoms of pityriasis capitis, without any adverse effects.

Keywords: Beetroot extract, *Cuscuta reflexa*, pityriasis capitis, Unani medicine

Introduction

Pityriasis capitis is the persistent, relapsing inflammatory condition with visual perception of individually distinguishable flakes on the scalp, in the hair, or on the clothing.^[1] The development of dandruff is predicted to be determined by colonization of yeast *Malassezia furfur*, sebum production, and individual susceptibility. Dandruff is a localized variant of seborrheic dermatitis confined to the scalp and has itching, flaking, and redness of scalp with mild inflammation.^[2] No residents in any geographical area would have passed through freely without being affected by dandruff at some stage in their life.^[3] Although the exact etiology of dandruff is not clear up till now. Besides physical discomfort such as itching, shedding of flakes from scalp dandruff is socially embarrassing and impacts negatively on patient's self esteem. It has significant negative effects on patient's quality of life (QOL) in the form of psychological distress and confidence.^[4] In Unani

medicine, pityriasis capitis (dandruff) is termed as *Hazāz*, and considered a disease of *Sū'-i-Mizāj Māddi Balghami* and *Sū'-i-Mizāj sawdāwi* (deranged phlegmatic and melancholic humors).^[5] Conventional treatment of dandruff comprises frequent use of shampoos and lotions containing azoles, namely ketoconazole, fluconazole, keratinolytic agents, salicylic acid, sulfur, zinc pyrithione, coal tar, steroids, and selenium sulfide.^[6] However, all these treatment options are costly, and the chances of recurrence also remain high. These antidandruff agents have to be used for a long period, usually for few months, and leave the scalp dry, which leads to frequent scalp irritation, and also premature greying of hair.^[7] Some of these agents may lead to some detrimental effects such as skin irritation from zinc pyrithione; carcinogenic effects of coal tar when used in excess; burning sensation from repetitive use of salicylic acid; and itching, rashes, and allergy from ketoconazole.^[8] Therefore, the thrust of research to the medical fraternity, including Unani medicine. Classical Unani literature deals with a number of time-tested

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and cost-effective therapeutic regimens and formulations for the management of *Ḥazāz* (dandruff). There are drugs that act by balancing *akhlāt fasida* (morbid humors), *ratoobat i mizāj* (moistness of temperament), and *musaffiyāt* (blood purifiers).^[9] Drugs possessing actions such as *Mushil-i-Sawdā* (purgative of melancholy), *Mulattif* (demulcent), *Jāli* (detergent), *Muhallil-i-Awram* (anti-inflammatory), *Islāh-e-jigar* (hepatotonic), and *Muharrrik* (stimulant) have been recommended topically.^[10] *Joshānda Afīmūn*, a polyherbal preparation, contains *Haleela Siyah*, possessing actions such as *Muhallil-e-Awrām* (anti-inflammatory), *Mundij e sawdā* and *mulayyin* (laxative) activities and topical application of *Joshānda Khubāzī*, *Āb-i-Chuqandar* and *borah Armanī* as *jāli* (detergent) *muḥarrrik* (stimulant) *da'afe taffun* (anti-microbial) drugs often recommended in *Ḥazāz*.^[11,12] Therefore, this study was designed to compare the effects of *Joshānda Afīmūn* as a common orally used preparation with local application over the scalp of *Āb-i-Chuqandar* and *Bora Armanī* versus *Joshānda Khubāzī* in *Ḥazāz* (pityriasis capitis). The study outcome in both the groups was evaluated in comparison of baseline findings and after treatment with scales on scalp and itching of scalp and reversal of Adherent Scalp Flaking Score (ASFS). Scalpdex (questionnaire for QOL), Wood's lamp characteristic, and photographs of the affected area.

Materials and Methods

Study design

This study was designed as a randomized comparative clinical trial.

Ethical consideration

This study was approved by the Institutional Ethical Committee (IEC) for biomedical research of NIUM with IEC No: NIUM/IEC/2020-21/029/JT/02) on 15/07/2021. Written informed consent was obtained from all study participants.

Clinical Trials Registry

This study was registered in the Clinical Trials Registry of India in March 2022 with the clinical trial registration number – CTRI/2022/03/052903.

Study subjects

Participants' information sheets were made available to the patients and their caretakers. Written informed consent was sought from all patients before enrollment.

Sample size

The sample size was estimated considering the mean and standard deviation (SD) from the previous study,^[12] using the formula $N = \frac{(r+1)(Z\alpha + Z1-\beta)^2 \sigma^2}{rd^2}$, considering the

calculated sample size $Z\alpha$: with the level of significance of 5% this is 1.96, the sample size was derived as $n = 32$, and including 10% dropout, it was set to be 36.

Randomization, blinding, and concealment

The actual number of subjects screened for the study was 48, of which 35 eligible subjects were randomized into two groups, i.e., test group ($n = 17$) and control group ($n = 18$). Randomization was done using a computer-generated random number list. Participants were blinded to the allocation until the end of the study using similar containers to distribute the medicine.

Drug preparation

The test drugs *Āb-i-Chuqandar* (beetroot extract) and *borah Armanī* were prepared according in the National Institute of Unani Medicine (NIUM) pharmacy. The raw drug was purchased from the local market of Bengaluru. It was verified and authenticated by the chief pharmacist of NIUM. The patients were advised to soak *Joshānda Afīmūn* (*Cuscuta reflexa* extract) in water overnight, and a decoction was prepared the next morning by boiling the water until the volume of the water was reduced to halved. *Āb-i-Chuqandar* was made by crushing the beetroot in the mixer, and the filtered extract was mixed with 7 g of *Borah Armanī* (Armenian bole) as a preservative and given to the patient in the form of shampoo, packed in the air-tight bottles.

Intervention

Patients underwent clinical assessment before initiation of drug administration to ascertain meeting the inclusion criteria. Eligible patients with a history of dandruff, presence of scales, and itching of scalp were randomized into two study groups. The test group subjects received 15 g of *Joshānda Afīmūn* (*C. reflexa*) two times per day after meal with topical application of *Āb-i-Chuqandar* (beetroot extract) for 21 days. Similarly, the control group subjects received 15 g of *Joshānda Afīmūn* (*C. reflexa*) two times per day after meal with topical application of *Joshānda Khubāzī* (*M. sylvestris* extract) for 21 days. Patients of both the groups were asked to observe abstinence from hair oil application and not to use any concomitant therapy throughout the trial.

Efficacy assessment

Assessment of efficacy was determined based on objective parameters, namely Investigator Global Assessment (IGA) for itching, reversal of ASFS, and Scalpdex questionnaire for QOL. After enrollment, study patients were asked to visit the hospital every 7th, 14th, and 21st day (three visits after the first visit). During each visit, patients were assessed for the improvement in parameters. Patients were also encouraged to contact the researcher at any time during the course of the trial to report adverse effects.

Statistical analysis

Descriptive and inferential statistical analysis was carried out in the present study. Results on continuous measurements were presented on mean \pm SD, and

results on categorical measurements were presented in number (%). The Chi-square/Fisher's exact test was used; $P < 0.05$ was considered statistically significant. Primary outcome and secondary outcome measures were compared methodology from baseline versus various follow-ups (1st, 2nd, and 3rd) using nonparametric, McNemar's test. $P < 0.05$ was considered statistically significant. Data were analyzed using IBM SPSS Statistics (IBM Corp., Armonk, NY, USA), was used to generate graphs, tables, etc.

Results

Study flow and baseline characteristics of the patients

A total of 48 patients were screened for eligibility, of which 36 subjects met the inclusion criteria and agreed to participate in the study, where 17 subjects were assigned to the intervention group and 18 to the control group; one subject dropped from the study in the control group, and eventually 35 subjects completed the study [Figure 1].

The mean age of the participants in the trial was 26.53 ± 54.10 years in the test and control groups, respectively ($P = 0.442$). The other demographic data of the participants are shown in Table 1. None of the baseline clinical characteristics of the patients had a significant difference between the two groups of the trial.

Clinical response

All the subjective and objective parameters showed a significant reduction in the test group, but in the control group, reductions were observed in itching alone. There was a significant reduction in scales of scalp and itching of scalp in both the test and control groups ($P < 0.0001$), whereas the reduction in scales of scalp was statistically significant in the test group ($P = 0.001$), but not in the control group ($P = 0.99$). Similarly, there was a significant decrease in scalp itching in the test group ($P = 0.0001$) but not in the control group ($P = 0.09$). The difference between the levels of scales of scalp and itching of scalp was found to be statistically significant before and after treatment in both the test and control group ($P < 0.001$).

On comparison of the results of pre- and posttreatment among the groups, the results were statistically significant ($P < 0.001$). However, between the groups, there was no significant improvement ($P = 0.99$). The changes in all the subjective and objective parameters are presented in Table 2.

Discussion

Joshānda Khubāzī (*M. sylvestris*) and *Joshānda Afīmūn* (*C. reflexa*) were compared for their ability to alleviate *Hazāz* (dandruff) symptoms with *Āb-i-Chuqandar* (beetroot extract) and *Bora Armanī*. Based on the results, *Joshānda Afīmūn* and *Āb-i-Chuqandar* may have antidandruff properties and effectively restore the levels of scalp flora in dandruff patients.^[13-15]

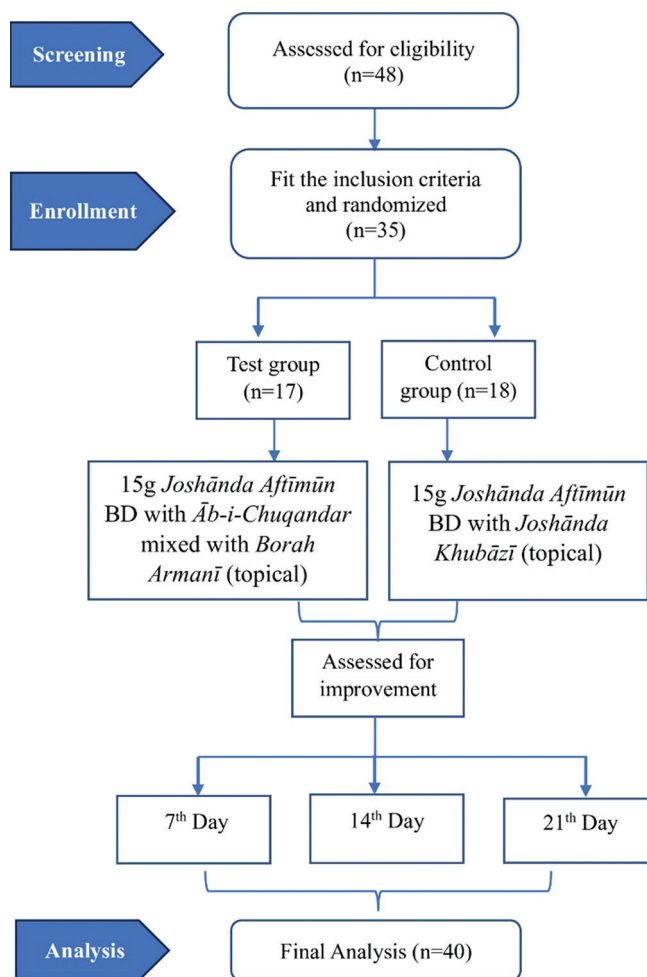


Figure 1: CONSORT flow diagram of the study

Table 1: Baseline demographic data of the trial participants

Variables	Test group, n (%)	Control group, n (%)	P
Age (years)	26.53±5.410	26.61±8.58	0.974
Gender			
Male	5 (29.4)	12 (66.7)	0.028
Female	12 (70.6)	6 (33.33)	
Occupation			
Professionals	1 (5.9)	5 (27.8)	0.033
Clerks	3 (17.6)	0	
Unemployed	4 (23.5)	10 (55.6)	
Socioeconomic status			
Upper	0	1 (5.6)	0.614
Upper middle	7 (41.2)	5 (27.8)	
Lower middle	3 (17.6)	5 (27.8)	
Mizāj			
Balghami	2 (11.8)	9 (50.0)	23.3
Safrāwi	2 (11.8)	2 (11.1)	
Sawdawī	13 (76.5)	7 (38.9)	

Several pharmacological and clinical investigations have explored the role of Unani formulations in the

Table 2: Comparison of the changes in objective parameters of patients after the interventions

Parameters	Follow-up	Test group (n=17)	Mean difference percentage difference	Control group (n=18)	Mean difference percentage difference	Intergroup (P)
ASFS	BL	3 (17.6)	11.8	14 (77.8)	66.7	<0.0001
	F3	1 (5.9)		2 (11.1)		
Wood's lamp fluorescence	BL	17 (100.0)	88.2	15 (83.3)	61.1	<0.0001
	F3	2 (11.8)		4 (22.2)		
IGA	BL	10 (58.8)	52.9	12 (67.7)	66.7	<0.0001
	F3	1 (5.9)		0		

Parameters	Follow-up	Test group (n=17), mean±SD	Control group (n=18), mean±SD	Intergroup, P
TSS	BL	72.06±38.41	70.83±35.61	1
	F3	38.41±13.21	8.33±14.85	0.276
TES	BL	262.06±230.39	262.50±242.42	0.64
	F3	0.00±0.00	0.00±0.00	0.12
TES	BL	16.18±29.237	13.89±29.978	0.683
	F3	0.00±0.00	0.00±0.00	1

ASFS: Adherent Scalp Flaking Score, IGA: Investigator Global Assessment Score, TSS: Total symptom score, TES: Total emotional score, SD: Standard deviation

management of *Hazāz* (pityriasis capitis/dandruff). Previous studies have reported the efficacy of *Joshānda Afīmūn* in correcting deranged humoral balance, expelling morbid humors, and exerting antifungal and anti-inflammatory activities. *In vitro* models have demonstrated its antioxidant and sebum-modulating potential, while clinical observations suggest a positive role in scalp disorders.^[16,17] *Aab-e-Chuqandar* is rich in betalains, nitrates, and antioxidants. Beetroot has been shown to improve microcirculation, modulate oxidative stress, and restore scalp health. Limited clinical trials exist, but preliminary findings support its role as an adjunct in dermatological conditions.^[18] *Joshānda Khubāzī* traditionally used in Unani medicine for its cooling, demulcent, and anti-inflammatory effects. *Khubāzī* decoctions have been studied for skin conditions, including eczema, pruritus, and inflammatory dermatoses. Experimental evidence highlights its soothing effect on irritated scalp tissue, along with antimicrobial properties.^[19]

Future research directions should focus on larger multicentric clinical trials to validate the efficacy and safety of these Unani formulations in diverse population and longer follow-up durations and to elucidate molecular pathways (antifungal, anti-inflammatory, antioxidant, and sebum-regulating effects) through *in vitro* and *in vivo* models. Furthermore, exploring novel dosage forms such as shampoos, gels, or nanoformulations for better patient compliance can help in future, and by aligning Unani formulations with dermatological guidelines for dandruff management, ensuring wider acceptance may be integrated into clinical practice.

As a result, we can confidently say that the anti-inflammatory and antioxidant qualities of *Joshānda Afīmūn* (*C. reflexa*) and *Āb-i-Chuqandar* (beetroot extract) inhibit the formation of scalp flakes and scales. Based on the

qualities and scientific data given above, it can be inferred that *Āb-i-Chuqandar* (beetroot extract) and *Joshānda Afīmūn* (*C. reflexa*) can be recommended as an alternate treatment for dandruff patients.

Conclusion

Despite the trial's limitations, this randomized controlled clinical trial provides evidence that *Joshānda Afīmūn*, along with the test drug *Āb-i-Chuqandar*, is effective in reducing scales of scalp and increasing the QOL and is superior to the control drug, i.e., *Joshānda Khubāzī*, with respect to efficacy on reducing itching of scalp.

Acknowledgments

We thank the participants and staff who assisted this study and also acknowledge the efforts of the hospital staff of NIUM, Bengaluru, Karnataka, for providing facilities during the trial.

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Conflicts of interest

There are no conflicts of interest.

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Evaluating the Effectiveness of *Saussurea Lappa* Oil (Rogane Qust) in Carpal Tunnel Syndrome: An Open-label Clinical Trial

Abstract

Background: Carpal Tunnel Syndrome (CTS) results from compression of the median nerve at the wrist, causing pain, numbness, tingling, and weakness in the hand and arm. It is often linked to repetitive wrist movements, trauma, or conditions like diabetes. Conventional treatments, including corticosteroids, splints, and surgery, may not fully relieve symptoms and can have side effects. The Unani medical system offers alternative remedies, such as *Saussurea costus* (Falc.) Lipsch. oil, known for its analgesic, anti-inflammatory, and neuroprotective properties. This study assesses its safety and effectiveness in managing CTS. **Materials and Methods:** An open-label interventional clinical trial included 15 CTS patients who applied *Saussurea costus* (Falc.) Lipsch. oil (5 ml) topically over the carpal tunnel area once daily for 15 days. Pain was measured using the Visual Analog Scale (VAS), while symptom severity and functionality were assessed with the Boston Carpal Tunnel Questionnaire (BCTQ). Baseline and posttreatment scores were compared, with statistical significance set at $P < 0.05$. **Results:** Significant improvements were observed in both VAS and BCTQ scores following treatment. The mean \pm standard deviation changes in VAS and BCTQ scores were 2.9 ± 1.0 and 10.1 ± 5.5 , respectively, with a $P = 0.001$. No adverse effects were reported during or after the study. **Conclusion:** *Saussurea costus* (Falc.) Lipsch. oil (*Roghan-i-Qust*) demonstrated significant efficacy and safety in reducing CTS symptoms, including pain and numbness, within 15 days of treatment. These findings highlight its potential as an effective and safe therapeutic option for CTS management (CTRI/2020/03/024071, March 19, 2020).

Keywords: Carpal Tunnel Syndrome, Khadar, Roghan-i-Qust, Unani Medicine, Waj'-al-'Aşāb

Introduction

Carpal Tunnel Syndrome (CTS) is a prevalent condition marked by wrist pain, numbness, and a tingling sensation.^[1] CTS is responsible for 90% of all neuropathies and is the most common neuropathy caused by median nerve entrapment.^[2] CTS affects approximately 2.7%–5.8% of the general adult population.^[3] Increased pressure within the carpal tunnel leads to compression of the median nerve, resulting in the development of CTS.^[4] CTS is more prevalent in females than males, with women being 3–10 times more likely to develop the condition.^[5,6] The primary causes of CTS often include genetic factors, frequent repetitive wrist motions like those associated with typing or operating machinery, as well as conditions such as obesity, autoimmune diseases such as rheumatoid arthritis, and physiological changes during pregnancy.^[7,8] Geoghegan *et al.* identified various risk factors linked to CTS.^[9] These include a history of wrist

fractures, rheumatoid arthritis, osteoarthritis affecting the wrist and carpus, obesity, diabetes, and the use of medications such as insulin, sulfonylureas, metformin, and thyroxine.^[10] The mechanisms behind median nerve compression and traction are believed to be complex and remain not fully understood.^[11] The process involves a combination of mechanical trauma, elevated pressure, and ischemic damage to the median nerve within the carpal tunnel. Under normal conditions, pressure within the carpal tunnel typically ranges from 2 mmHg to 10 mmHg. However, changes in wrist positioning can lead to significant fluctuations in fluid pressure within the tunnel.^[12] Wrist extension can elevate pressure within the carpal tunnel to more than ten times its baseline level, while wrist flexion results in an eightfold increase in pressure.^[13] Patients commonly experience symptoms such as numbness, tingling, and pain that tend to worsen at night. Additional complaints often include weakness, clumsiness, and

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changes in temperature sensation.^[14] Various specialized tests with differing levels of sensitivity and specificity are available for diagnosing CTS, but electromyography and nerve conduction studies remain the cornerstone diagnostic methods.^[15] Other clinical or specialized examinations cannot definitively diagnose CTS but are helpful in excluding alternative conditions.^[16,17] The clinical physical examination may involve assessing sensory and motor deficits, as well as checking for signs of thenar muscle atrophy.^[18,19] The differential diagnosis helps differentiate CTS from conditions like carpometacarpal arthritis of the thumb, which is characterized by severe pain during thumb movement, a positive grind test, and specific radiographic findings.^[20] The treatment of CTS varies based on the severity of the condition and may include splinting, corticosteroid injections, physical therapy, therapeutic ultrasound, and yoga.^[21] The Unani texts described *Waj'-al-'Aṣāb* (neuralgia), *Khadar* (paresthesia, hypoesthesia, tingling, and numbness),^[22] and that etiology of nerve compression as due to imbalance of body humors.^[23] Unani scholars proposed that the underlying cause of pain is related to an imbalance in the organ's temperament (*Sūi Mizājī*) and attributed it to pressure on a nerve branch (compressive mononeuropathy), which aligns with the pathophysiology of CTS.^[24]

CTS-like condition was recovered with drugs and regimens, local application of *Dimād*, *Ṭilā* and *Roghaniyāt* and simple *Riyādat*. Apart from this, compound drugs are being indicated for neuralgic pain, such as *Roghan-e-Farfiyoon*, *Roghan-e-Habbul Ghar*, *Roghan-e-Khayri*, *Majoon-e-Khadar Habb-e-Sheetraj*, *Habb-e-Asab*, *Habb-e-Azraqi*, one out of such formulations *Roghan-i-Qusṭ* contains ingredients like, *Qusṭ*, *Aaqarqarha*, *Farfiyun*, *Jund baidastar*, *Filfil Siyah*, and base *Roghane Kunjad*.^[25] These drugs in combination will exert local analgesic, dissolvent, neuroprotective, anti-inflammatory, deobstruent effects. Therefore, it was hypothesized that the *Roghan-i-Qusṭ* drug would be effective in CTS. Hence, to validate the effectiveness of *Roghan* in relieving pain (neuralgia). This study aims to evaluate the effectiveness and safety of *Roghan-i-Qusṭ* in alleviating symptoms of CTS.

Materials and Methods

Study design and procedure

This study was designed as an open-label, interventional clinical trial with a pre- and postanalysis framework. All participants were initially provided with a comprehensive explanation of the study procedures, including its objectives, benefits, and potential risks. The clinical study was carried out at the Department of Moalajat, National Institute of Unani Medicine in Bengaluru, over 4 months, from December 2020 to March 2021, following ethical approval from the Institutional Ethical Committee for Biomedical Research with IEC No: NIUM/IEC/2018-19/008/Moal/dated 21/03/2019 and CTRI vide No: CTRI/2020/03/024071 on March 19, 2020. The study protocol was designed in

accordance with the ethical standards of GCP and the Declaration of Helsinki. Informed consent was obtained from each participant who chose to take part in the study.

Participants

Patients were recruited from the OPD of the NIUM, Bengaluru. The inclusion criteria consisted of individuals aged 20–65 years, of either gender, with a confirmed diagnosis of CTS and positive results for Phalen's test, Tinel's sign, and Durkan's sign, along with a willingness to participate and follow study guidelines. Exclusion criteria encompassed cases with thenar muscle atrophy, negative results for Phalen's test, Tinel's sign, and Durkan's sign, as well as pregnant and lactating women.

Intervention/collection, identification, and method of preparation

The ingredients for the test formulation [Table 1] were acquired from the NIUM pharmacy, Bengaluru, and were thoroughly authenticated by the Chief Pharmacist at NIUM. The formulation was prepared in the NIUM pharmacy following Good Manufacturing Practices (GMP) and the procedures outlined in the formulary.

Drug dosage form and their route of administration

The patient was advised to apply 5 ml oil once daily in a thin layer over the carpal tunnel area.

Outcomes

The efficacy outcome was assessed by comparing baseline findings with those from subsequent follow-ups. Primary outcome included the Visual Analogue Scale (VAS) and secondary outcome is the BCTQ, while subjective parameters assessed included the affected wrist, paresthesia, hypoesthesia, and functional limitations.

Sample size estimation

The sample size was calculated considering the mean and standard deviation of a previous study with α error 0.05 and β error of 0.20, where the mean pain scale was 2.46 with standard deviation (SD) 2.96, following formula was used to determine the sample size. $N = (Z\alpha)^2 S^2/d^2$. Where, N = sample size required μ_1 = Mean changes in pain scale from baseline in previous study 2.46 μ_2 = Mean changes in pain scale from baseline in proposed drug 0.20, $\mu_1 - \mu_2$ = clinically significant difference, SD = Standard deviation, $Z\alpha$ = level of significance, for 5% this is 1.64, $Z\beta$ = power, for 80% this is 0.84. Based on the required improvement in pain scale (VAS), the calculated sample size was 17 participants.

Allocation of subjects

A total of 26 subjects were screened for the study. Of these, seven did not meet the inclusion criteria, two declined to participate, and two were lost to follow-up. Ultimately, 15 subjects were enrolled and completed the study. All participants were first assessed for safety, and after baseline

measurements were taken, they were administered the test drug, *Roghan-i-Qust*, Once daily.

Follow-up during treatment

The research period of 15 days was divided into four follow-up visits (0th, 5th, 10th, and 15th day) that were made at the 5th day interval. During each follow-up, patients were questioned about any changes in their symptoms, whether progression or regression, and the details were recorded in the CRF.

Statistical analysis

The study also incorporated a per-protocol analysis to evaluate outcomes among participants who strictly adhered to the study protocol. Only those patients who completed the assigned intervention as per the scheduled visits and complied with the treatment regimen were included in this analysis. Participants who deviated from the protocol, missed key follow-ups, or discontinued treatment were excluded. This approach allowed for assessing the true efficacy of the intervention under ideal adherence conditions, with statistical significance evaluated using appropriate tests and *P* values calculated accordingly.

Results

Participants and baseline characteristics

Between December 2020 and March 2021, after screening out of 26 patients, a total of 17 participants met the inclusion criteria. Among the remaining 09 participants, 07 did not meet the inclusion criteria, and 02 declined to participate. Out of 17 patients initially enrolled in the

study, 15 completed the treatment regimen successfully, and 2 participants were lost to follow-up, discontinued the intervention, and were excluded from the analysis. Statistical analysis was conducted on the data obtained from the 15 participants who completed the therapy. Detailed information about the study flow is demonstrated in Figure 1. Baseline demographic and clinical characteristics are summarized in Table 2.

Effect of treatment outcome

Primary outcome: Visual Analog Scale

Wrist pain was evaluated by using the VAS. The VAS assessment score (Mean + SD) at baseline was 6.0 ± 0.5 , at F1 5.3 ± 0.7 with the paired difference of 0.7 ± 0.5 with $P = 0.001$, at F2 4.4 ± 0.7 with a paired difference of 1.6 ± 0.81 with $P = 0.001$, at F3 3.1 ± 0.7 with paired difference 2.9 ± 1.0 with $P = 0.001$. The *P* value of VAS scale score with respect to baseline (0th day) at F1 (5th day), F2 (10th day), and F3 (15 h day) was highly significant, i.e., 0.001 and indicate significant improvement in pain [Table 3].

Secondary outcome: Boston Carpal Tunnel Questionnaire score

Boston score was evaluated (mean + SD) at baseline was 37.1 ± 4.5 , at F1 34.1 ± 6.2 with the paired difference of 2.9 ± 3.0 with *P* value 0.002, at F2 30.6 ± 7.7 with a paired difference of 6.5 ± 5.1 with $P = 0.001$, at F3 27.0 ± 7.7 with paired difference 10.1 ± 5.5 with $P = 0.001$. The *P* value of Boston (BCTQ) scale score with respect to baseline (0th day) at F1 (5th day), F2 (10th day) and F3

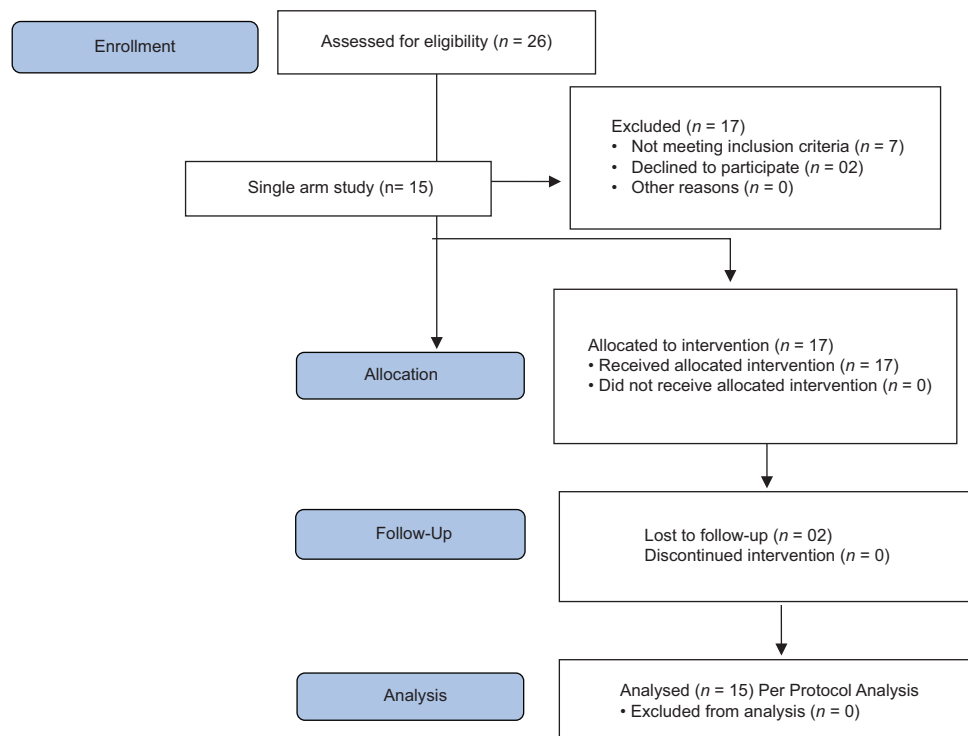


Figure 1: Study flow chart

(15 h day) was highly significant, i.e., 0.001 and indicate significant improvement [Table 3].

Subjective parameters

Subjective parameters revealed improvement in terms of affected wrist, paresthesia, hypoesthesia, and functional limitations in patients of CTS [Figure 2].

Assessment of safety and tolerability

The safety and tolerability profile were based on assessment of hematological parameters such as Hb%, total leukocyte count, differential leukocyte count, and erythrocyte

Table 1: List of ingredients of test formulation (Roghan-e-Qust)

Unani name	Scientific name/family	Parts used	Weight (g)
Qust	<i>Saussurea lappa</i> /Asteraceae	Root	120
Filfil Siyah	<i>Piper nigrum</i> /Piperaceae	Fruit	120
Aqerqarha	<i>Anacyclus pyrethrum</i> / Asteraceae	Root	120
Farfiyun	<i>Euphorbi resinifera</i> / Euphorbiaceae	Resin	120
Jund Bedastar	<i>Castoreum canadensis</i> / Castoridae	Secretion	020
Roghan-e-Kunjad	<i>Sesamum indicum</i> /Pedaliaceae	Oil	250

Table 2: Demographic and clinical profile of the participants

Characteristics	Number of participants (%)
Age (years), mean±SD (range)	44.6±6.7
Gender	
Male	4 (26.7)
Female	11 (73.3)
Socioeconomic status	
Upper	
Upper middle	4
Lower middle	9
Upper lower	1
Mizaj (temperament)	
Balghami (phlegmatic)	12 (80)
Şafrāwī (bilious)	2 (13.3)
Sawdawī (melancholic)	1 (6.7)
Occupation	
Skilled	6 (40)
Semiskilled	8 (53.3)
Unskilled	1 (6.7)
BMI	
18.6–24.9	2 (13.3)
25–29.9	4 (26.7)
>30	9 (60)
Duration of illness (months)	
<1	4 (26.7)
1–3	5 (33.3)
>3	6 (40)

BMI: Body mass index, SD: Standard deviation

sedimentation rate. These investigations were carried out before starting and after completion of treatment. No statistically significant difference was found between the pretest and posttest comparisons. The study found that all safety parameters remained within normal range values, with no statistically significant differences observed.

Discussion

In this prospective, single-arm, open-label, interventional clinical trial employing a pre- and postanalysis design to evaluate the efficacy of the polyherbal formulation *Roghan-i-Qust* in the management of CTS. This study provides evidence supporting the use of a polyherbal formulation to alleviate the symptoms of CTS. In addition, the findings offer valuable insights into the epidemiology of CTS within the study population. The mean age of the participants, 44.60 ± 6.7 years, aligns with previous studies by Guan *et al.*, Dale *et al.*, and Blumenthal, which report a peak incidence of CTS occurring between the ages of 40–50.^[10,26,27] The gender distribution in this study favored females (73.33%), consistent with previous findings that attribute this predisposition to potential sociocultural factors or hormonal influences.^[28,29] Padua *et al.* noted that women generally exhibit lower thresholds and tolerance levels for reported pain. These findings align with the present study. The *Mizāj* (temperament) classification revealed diverse humoral compositions among participants, which may influence susceptibility to CTS. Notably, 80% of the participants exhibited a phlegmatic temperament. In this study, the majority of patients (80%) were found to have a *Balghami Mizāj* (phlegmatic temperament), followed by 13.3% with *Şafrāwī* (bilious temperament) and 6.7% with *Sawdawī* (melancholic temperament). This finding aligns with the Unani concept of *Mizāj* (temperament) in *Akhlāṭ* (humors), as *Khidr* and *Waj‘-al-‘Aşāb* are categorized as *Amrād-e-Balghamiya* (phlegmatic disorders) in Unani literature. Zakaria Al-Razi, stated that nerve obstruction results from the congestion of cold, dense substances (*Imtilā-i-Ghalīz Akhlāṭ*).^[30,31] The outcome measurements

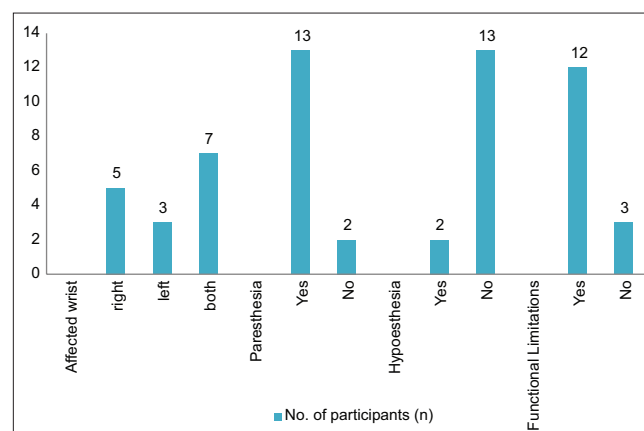


Figure 2: Participant's information about affected wrist, paraesthesia, hypoesthesia, and functional limitations

Table 3: Efficacy of intervention

Parameters	BL	F1	F2	F3	P
Wrist pain on VAS	6.0±0.5	5.3±0.7	4.4±0.7	3.1±0.7	0.001
Boston CTS	37.1±4.5	34.1±6.2	30.6±7.7	27.0±7.7	0.001

VAS: Visual Analog Scale, CTS: Carpal Tunnel Syndrome, BL: Baseline

demonstrated a significant reduction in both the VAS for wrist pain and the BCTQ scores, with a highly significant $P < 0.001$ for each assessment. The active ingredients in *Roghan-i-Qust*, including *Qust* (*Saussurea costus* (Falc.) Lipsch.), *Filfil Siyah* (*Piper nigrum* L.), *Aaqarqarha* (*Anacyclus pyrethrum* L.), *Farfiyun* (*Euphorbia resinifera* Berg.), *Jundbedastar* (*Castoreum Canadensis* Kuhl), and *Roghan-e-Kunjad* (*Sesamum indicum* L.), are known for their well-documented analgesic and anti-inflammatory properties. A previous study carried out by Aswi et al. and Tag et al. demonstrated that *Saussurea costus* (Falc.) Lipsch. possesses potent analgesic and anti-inflammatory activities, which coincide with the findings of the present study.^[31,32] Previous studies have highlighted the therapeutic potential of the individual components in this formulation. Several *in vitro* and *in vivo* pharmacological studies have suggested that these ingredients act as inhibitors of Tumor Necrosis Factor-alpha (TNF- α), 5- α reductase, and suppress the proliferation of lymphocytes. In addition, they are known to contain bioactive compounds such as *Saussurine*, resins, inulin, tannins, sesquiterpene lactones, essential fatty acids, β -carotene, lutein, and calcium, reported for analgesic, anti-inflammatory, and neuroprotective effects.^[31,32] *Saussurea costus* (Falc.) Lipsch. have been reported to exert analgesic, anti-inflammatory, and neuroprotective effects, potentially benefiting CTS management.^[33] There are several mechanisms of action postulated, such as (i) saussurine is an analgesic and anti-inflammatory agent. It suppresses the production of pro-inflammatory cytokines such as TNF- α , interleukin (IL)-1 β , and IL-6, and suppresses COX-2 and iNOS pathways, reducing inflammation. This mechanism helps alleviate nerve compression and pain in CTS, (ii) resins from *Saussurea costus* (Falc.) Lipsch. contain bioactive molecules with potent anti-inflammatory properties. They reduce oxidative stress and modulate Nuclear factor kappa B (NF- κ B) signaling, which regulates inflammatory responses in damaged tissues, including compressed nerves, (iii) inulin enhances gut microbiota, indirectly influencing systemic inflammation. By reducing systemic pro-inflammatory mediators and improving immune balance, it may help in mitigating the inflammatory cascade in CTS, (iv) tannins are strong antioxidants and anti-inflammatory agents. They scavenge reactive oxygen species (ROS) and inhibit lipid peroxidation, reducing oxidative damage to the median nerve. Tannins also stabilize cell membranes, preventing further damage to nerve cells, (v) sesquiterpene lactones exhibit anti-inflammatory and analgesic effects

by inhibiting NF- κ B activation and the production of inflammatory mediators.^[34] These compounds also modulate pain perception by acting on TRP ion channels involved in nociception, (vi) essential fatty acids support membrane stability and help reduce neuroinflammation by inhibiting the production of prostaglandins and leukotrienes. They also enhance nerve repair and regeneration by supporting lipid metabolism, (vii) these carotenoids protect nerve cells by neutralizing ROS and preventing oxidative damage.^[35] They also reduce inflammation by modulating inflammatory signaling pathways such as NF- κ B and MAPK, (viii) calcium contributes to neurotransmission and nerve function.^[35] Proper calcium signaling is critical for nerve repair and function, reducing nerve degeneration and associated pain in CTS.^[31,32]

Hence, the aforesaid polyherbal Unani formulation may be beneficial in the management of CTS. Our findings align with these studies, suggesting that the combined formulation of *Roghan-i-Qust* harnesses the synergistic effects of its active ingredients, making it an effective treatment for CTS. There are several limitations to consider when interpreting the findings of this study. A key limitation of this study was its small sample size, which could restrict the generalizability of the results to a broader population, and second, a randomized controlled trial could provide stronger evidence of the efficacy of the test drug.

Conclusion

The findings of this study demonstrate that *Roghan-i-Qust* is both effective and safe in managing the symptoms of CTS. Significant improvements in pain and functional outcomes, as measured by VAS and BCTQ scores, were observed without any reported adverse effects. These results suggest that *Roghan-i-Qust* can be a valuable alternative treatment for CTS, particularly in cases where conventional therapies may not be suitable. Further randomized controlled trials with larger sample sizes are recommended to confirm these outcomes and explore the full potential of this polyherbal formulation.

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Conflicts of interest

There are no conflicts of interest.

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Evaluation of Acute Toxicity and Immunomodulatory Activity of a Polyherbomineral Formulation *Qurs Haiza* in Wistar Rats

Abstract

Objectives: *Qurs Haiza*, a polyherbomineral formulation, is used for various therapeutic purposes, especially cholera, in which the suppression of the immune system plays a key role in developing its pathology and complications. The scientific community always questions the safety of herbomineral products. Hence, the present study aimed at evaluating the acute toxicity and immunomodulatory activity of *Qurs Haiza* in albino Wistar rats to generate scientific data. **Methodology:** The acute toxicity of *Qurs Haiza* was evaluated at a single dose of 2000 and 5000 mg/kg b. w., in two groups of Wistar rats. The immunomodulatory study of *Qurs Haiza* at two dose levels was conducted against the cyclophosphamide-induced myelosuppression model in Wistar rats. The data were analyzed using one-way analysis of variance, followed by Dunnett's comparison test and Bonferroni's multiple comparison test. **Results:** No mortality was recorded at both dose levels of *Qurs Haiza*. However, mild toxic effects, including writhing reflex, piloerection, and some insignificant histological changes, were noted in the livers and kidneys of the rats belonging to AT-Group II and AT-Group III. The LD₅₀ of *Qurs Haiza* was found to be >5000 mg/kg, which comes under Category 5 of Organization for Economic Cooperation and Development, indicating very low acute toxicity in rats. The results of immunomodulatory activity showed a slight increase in hemoglobin and lymphocyte count and a significant increase in immunoglobulin G and immunoglobulin M in IM-Group IV. **Conclusions:** The overall findings have suggested that *Qurs Haiza* can be safely used for the treatment of infectious diseases, especially cholera, at the therapeutic dose level.

Keywords: Acute toxicity, immunomodulatory activity, *Qurs Haiza*, Unani medicine

Introduction

The herbal products described in the pharmacopoeias of alternative systems have been prescribed to patients throughout the world since olden days because of their natural origins and fewer side effects.^[1] Among all the alternative medicines of India, the Unani system has evolved into one of the most popular and beneficial modes of treatment for the past few decades. Despite the major advances in modern medicine, the Unani system still contributes extensively to developing the healthcare infrastructure.^[2] Henceforth, the World Health Organization has given global recognition to the Unani system in the category of complementary and alternative medicine. A global report has assessed that around 80% of the population consumes herbal drugs to fulfill their healthcare requirements. The formulations prescribed in the traditional systems are prepared with different parts of either plant, animal, or mineral-origin substances.^[3]

There is a lot of misunderstanding about herbal drugs that they are devoid of any adverse effects; however, a number of studies conducted from time to time have made it clear that these drugs produce several toxic effects, such as allergic reactions, hepatotoxicity, nephrotoxicity, neurotoxicity, cardiac toxicity, and even death.^[4] According to Unani physicians, drugs with a temperament of the 3rd and 4th degrees can produce serious adverse effects. Hence, as per their view, these drugs should be administered at the lowest doses. Various Unani pharmacologists have mentioned poisonous plants, among which *De Materia Medica*, written by Dioscorides in 64 CE, is of great importance. The toxicity of different vegetables, minerals, and animal-origin drugs is also described in the third and fourth volumes of *Al-Qanoon* (Canon of Medicine) compiled by Ibn Sina (980–1037 CE).^[5]

The immune system of the human body, constituted with different cells, tissues,

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and organs, helps to fight various communicable and noncommunicable diseases. It gives a powerful defense mechanism to the human body against viruses, bacteria, fungi, and other antigenic substances.^[6] It consists of a complex network of cells, proteins, and lymphoid organs arranged systematically to provide maximal protection against infections. The immune responses of the body are majorly categorized into two classes, i.e., (i) innate immunity and (ii) adaptive immunity (acquired immunity).^[7] The innate immunity is mainly responsible for producing different cytokines and chemotactic substances against microorganisms, whereas the acquired immunity identifies specific non-self-antigens in the existence of self-antigens.^[8] The immunomodulation refers to changes in the immune system through either increasing or decreasing immune responsiveness. We refer to the increasing and decreasing changes in immune responses as “immunostimulation” and “immunosuppression,” respectively. A number of studies have confirmed that many herbs, mostly botanicals and their active secondary metabolites, markedly produce immunomodulatory effects in various immunocompromised diseases.^[9]

Qurs Haiza, an important polyherbomineral compound, is used for the treatment of diarrheal disorders, including cholera. The individual ingredients of this compound formulation include Serpentine stone, *Zingiber officinale* Roscoe, *Piper nigrum* L., *Mentha arvensis* L., *Calotropis gigantea* (L.) Dryand., Black salt, and Salt of Lahore.^[10] Some of its components are known to exhibit immunomodulatory potential, but since no data are available on modern scientific parameters, first we evaluated the safety profile with reference to the acute toxicity and LD₅₀, followed by the immunomodulatory activity of an important Unani formulation, *Qurs Haiza*, in an animal model.

Methodology

Source of data collection

The animal housing and dosing in acute toxicity, and immunomodulatory activity and hematological investigations in the immunomodulatory activity were conducted at the Department of Unani Pharmacology, Regional Research Institute of Unani Medicine, Srinagar, Jammu and Kashmir, India. The histopathological evaluation of tissue specimens in the acute toxicity study was carried out at the Division of Veterinary Pathology, SKAUST-K, Shuhama, Srinagar, Jammu and Kashmir, India. The immunological investigations in immunomodulatory activity were done at the Vets for Pets Multispecialty Pet Polyclinic, Airport Road, Peer Bagh Chowk, Srinagar, Jammu and Kashmir, India.

Procurement of individual ingredients of *Qurs Haiza* and chemicals

The formulation of *Qurs Haiza* was procured from an authentic herbal shop located in Srinagar,

Jammu and Kashmir, India. The same was identified by Dr. Akhter H. Malik, University of Kashmir, Jammu and Kashmir, India, vide reference numbers 4401, 4402, 4403, and 4405 given to its botanical ingredients. Eosin (batch no. DA1D702569), formaldehyde solution (Batch no. CG0F700371), DPX mountant (batch no. DF0DF70623), acetone (batch no. SK1F710735), xylene (batch no. DC2D720221), paraffin wax, and benzene were obtained from Merck Life Science Private Ltd., Mumbai, India (400079). Hematoxylin (batch no. DF2DF72816) was obtained from HI Media Laboratories Pvt. Ltd., Mumbai, India (400086). Ethanol (lot no. 20200105) was obtained from Changshu Hongsheng Fine Chemical Co., Ltd., Changshu City, Jiangsu Province. Thiopentone sodium (batch no. 172439) was purchased from NEON Laboratories Ltd., Mumbai, India (400093). Endoxan-N injection (batch no. BUX1082) was procured from Euro Pharma Pharmaceutical Distributors, Srinagar, India. Sodium carboxymethylcellulose (CMC) (code 030772) was procured from High Purity Laboratory Chemicals Pvt. Ltd., 312, Mumbai, India (400002).

Composition of *Qurs Haiza*

100 mg of *Qurs Haiza* contains Zahar Mohra (*Serpentine stone*) (7.72 mg), Zanjabeel (*Zingiber officinale* Roscoe rhizome), Filfil Siyah (*Piper nigrum* L. fruits), Pudina Khushk (*Mentha arvensis* L. leaves), Gul-i-Madar (*Calotropis gigantea* (L.) Dryand. flowers), *Namak Siyah* (Black salt), and *Namak Lahori* (Salt of Lahore), each 15.38 mg.^[10]

Preparation of *Qurs Haiza*

First, a fine powder with the composition of *Qurs Haiza* was made and then sieved by passing it through a mesh (100-no.). The distilled water was then added to the powder to make a semisolid mass. The granules were then prepared from the semisolid mass by passing it through a sieve (20-no.). The granules were then dried in a hot air dryer at 50°C for 30 min. After drying, excipients were added to the granules, and tablets were prepared using a tablet-making machine.^[11]

Experimental animals

The healthy albino Wistar rats weighing 200–250 g were obtained from the Indian Institute of Integrative Medicine, Jammu, India. The Committee for Control and Supervision of Experiments on Animals guidelines were strictly followed for housing them in the polypropylene cages at 22°C ± 3°C, relative humidity 50% ± 20%, and on 12 h light/dark cycles. Before beginning the experimental trial, all the rats were under a quarantine period for 7 days and had free access to feed and water *ad libitum*.

Experimental design for acute toxicity study

The acute toxicity of *Qurs Haiza* was conducted by following the Organization for Economic and Development (OECD) guideline 423.^[12] The ethical approval with

reference number IAEC/RRIUM/Q.Haiza/19-20/2 was obtained from the Institutional Animal Ethics Committee of Regional Research Institute of Unani Medicine, Srinagar. Three groups comprising three female albino Wistar rats were as follows.

Acute toxicity Group I (AT - Group I)

A volume of 1 mL of distilled water was administered to this group by oral route daily for 14 days. This group was the plain control in the acute toxicity study design.

Acute toxicity Group II (AT - Group II)

A single dose of *Qurs Haiza* at the dose of 2000 mg/kg, dissolved in distilled water, was orally administered to the rats of this group.

Acute toxicity Group III (AT - Group III)

As per OECD guidelines, when no mortality was recorded in AT-Group II for 48 h, a single dose of *Qurs Haiza* at 5000 mg/kg, dissolved in distilled water, was orally administered to the rats of this group.

Observational parameters

Physical observations

Following drug administration, the physical observations, which include death, skin and fur, eyes, mucosa, behavioral patterns, locomotor activity, salivation, writhing reflex, convulsions, tremors, lethargy, sleep patterns, diarrhea, and coma, were done for 14 days as per the methods described in OECD guidelines 423.

Body weight, food intake, and relative organ-body weight

All the rats were individually weighed on the 1st day and every week during the whole trial. Their food intake was also measured daily, and the relative organ-body weight of the liver, heart, and kidney was calculated on the last day of the trial.

Histopathological examination of liver, kidney, and heart

On the 14th day, after an overnight fast, all the rats were sacrificed using an injection of thiopentone sodium (50 mg/kg IP). The visceral organs, including the liver, kidney, and heart, were collected from each rat to examine them grossly and microscopically. The visceral samples were cut into small pieces and then preserved in 10% phosphate-buffered formalin. Each slide was made by taking tissue sections (2–3 mm) and staining with hematoxylin and eosin for microscopic examination.^[13] The photomicrographs were taken using a Nikon Eclipse E200 Microscope Camera.

Experimental design for immunomodulatory activity

The immunomodulatory activity was conducted by following the method of Heroor *et al.*, 2013, with slight alterations on the cyclophosphamide-induced myelosuppression model. The immunity was suppressed by injecting an intraperitoneal injection of cyclophosphamide (30 mg/kg) in all groups

except the plain control.^[14] The maximum therapeutic dose of *Qurs Haiza* for human beings is 3 g, which was calculated using the formula (animal dose (mg/kg) = total human dose/average body weight (60 kg) multiplied by conversion factor (6.2) for rats.^[15] After conversion, the dose of *Qurs Haiza* was calculated to be 310 mg/kg b. w. The experimental design was as follows:

Immunomodulatory Group I (IM-Group I)

1% sodium CMC was administered daily by oral route to the rats of this group for 13 days. This group was the plain control in the immunomodulatory activity study design.

Immunomodulatory Group II (IM-Group II)

The rats of this group received 1% sodium CMC daily by oral route for 13 days and an intraperitoneal injection of cyclophosphamide (30 mg/kg) on the 11th, 12th, and 13th day. This group was the negative control in the immunomodulatory activity study design.

Immunomodulatory Group III (IM-Group III)

The rats of this group were administered *Qurs Haiza* at 310 mg/kg orally, dissolved in distilled water for 13 days, and cyclophosphamide (30 mg/kg IP), 1 h after giving the test drug on the 11th, 12th, and 13th day.

Immunomodulatory Group IV (IM-Group IV)

The rats of this group were administered *Qurs Haiza* at 620 mg/kg orally, dissolved in distilled water for 13 days, and cyclophosphamide (30 mg/kg IP), 1 h after giving the test drug on the 11th, 12th, and 13th day.

Parameters assessed

On the 14th day, all the experimental animals were euthanized using an injection of thiopentone sodium at a dose of 50 mg/kg IP. The blood sample from each rat was collected through cardiac puncture, and the hematological and serological indices, such as hemoglobin (Hb%), red blood cell count, platelet count, total leukocyte count (TLC), differential leukocyte count (DLC), immunoglobulin A (IgA), immunoglobulin G (IgG), and immunoglobulin M (IgM) were tested by following standard methods.

Statistical analysis

All the research values were incorporated into a designed worksheet and then transferred to the data editor GraphPad InStat and GraphPad Prism software version 9.4.1 for analysis. All the continuous variables assessed in both studies have been expressed as mean \pm standard error of the mean. One-way analysis of variance (ANOVA) was used to analyze all the parameters observed amongst different groups, followed by Dunnett's multiple comparison test for the acute toxicity study and Bonferroni's multiple comparison test for the immunomodulatory study. A repeated measure of ANOVA was also applied when observations of parameters were recorded more than twice.

The statistically significant value was considered to be significant at $P < 0.05$.

Results

Acute toxicity

Physical observations

Some abnormal physical signs, including sluggish movement, piloerection, writhing reflex, circling, Straub tail, tremors, and mild confusional state, were detected in the experimental rats, who received both dose levels of *Qurs Haiza*.

LD₅₀

The LD₅₀ of *Qurs Haiza* was found to be >5000 mg/kg, which comes under Category 5 of Organization for Economic Cooperation and Development, indicating very low acute toxicity in rats.

Body weight

On the 7th day, the body weight of rats belonging to AT-Group II and AT-Group III was found to be significantly reduced ($P < 0.001$) in comparison to the 1st day and significantly gained on the 14th day ($P < 0.001$) in comparison to the 7th day [Table 1].

Food intake

The daily food intake of AT-Group I, AT-Group II, and AT-Group III was recorded as 90.5 ± 7.03 , 84.1 ± 4.22 , and 83.5 ± 4.49 , respectively.

Relative organ-body weight

The relative organ-body weight of the liver of AT-Group I, AT-Group II, and AT-Group III was 3.33 ± 0.08 , 3.09 ± 0.27 , and 3.32 ± 0.24 , respectively. The relative organ-body weight of the kidneys of AT-Group I, AT-Group II, and AT-Group III was 0.68 ± 0.02 , 0.69 ± 0.03 , and 0.66 ± 0.01 , respectively. The relative organ-body weight of the heart of AT-Group I, AT-Group II, and AT-Group III was recorded as 0.45 ± 0.04 , 0.37 ± 0.02 , and 0.37 ± 0.01 , respectively.

Histopathological examinations

Gross examination of liver, kidney, and heart

The gross appearance of the liver, kidney, and heart in all groups was found to be normal; no remarkable changes were seen during the postmortem examination.

Table 1: Effects of *Qurs Haiza* on total body weight of rats in acute toxicity study

Group	1 st day	7 th day	14 th day
AT-Group I	223.6±8.51	206.6±7.85	225.6±3.84
AT-Group II	197±4.35	147.6±10.68**	211±6.55**
AT-Group III	201±9.71	170.6±4.97**	216±7.35**

** $P < 0.001$ (highly significant). Comparison between groups was made using one-way ANOVA followed by Dunnett's multiple comparison. Values are expressed as Mean±SEM ($n=3$). SEM: Standard error of mean, AT: Acute toxicity, ANOVA: Analysis of variance

Microscopic examination of liver, kidney, and heart

A predominant congestion in the hepatic central vein with perivascular cellular infiltration was seen in AT-Group II, while a significant degeneration of hepatic cells along with Kupffer cell proliferation was found in AT-Group III [Figure 1]. The renal tubular necrosis, severe congestion in the medulla, glomerular atrophy, and an increase in the Bowman's space with cellular infiltration were examined in AT-Groups II and III [Figures 2 and 3]. The histology

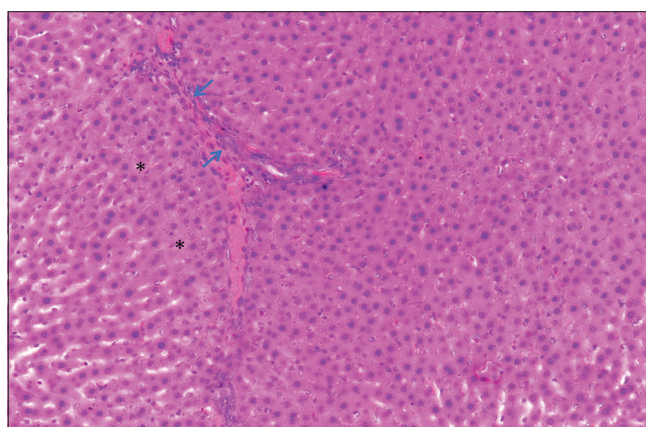


Figure 1: Liver of AT-Group III (degeneration of hepatocytes [*] along with Kupffer cell proliferation [arrow]) H and E ×20

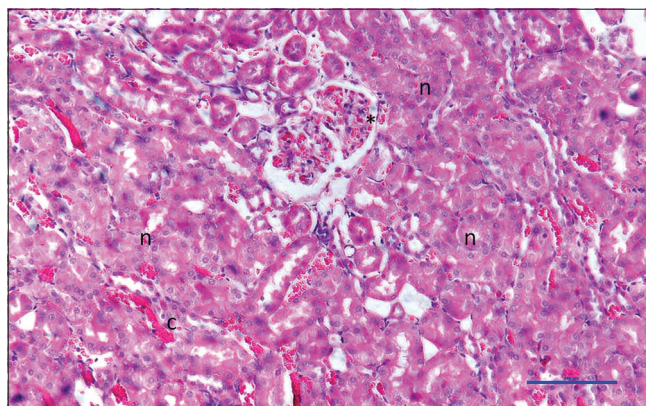


Figure 2: Kidney of AT-Group II (renal tubular necrosis [n], congestion [c] and increase Bowman's space with infiltration [*]) H and E ×20

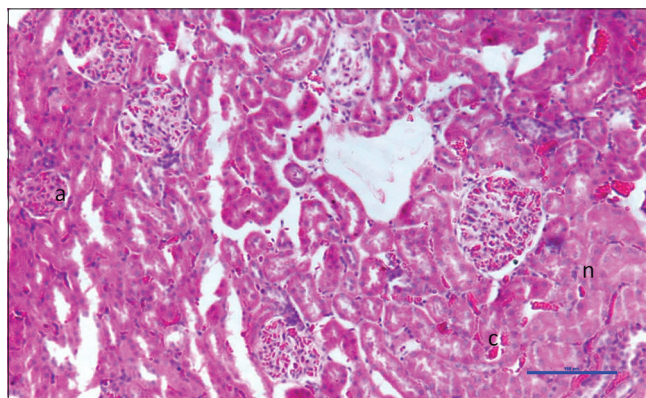


Figure 3: Kidney of AT-Group III (renal tubular necrosis [c], glomerular atrophy [a], medullary congestion [c]) H and E ×20

of the hearts of AT-Groups II and III exhibited disruption of muscle fibers with congestion and thickening of blood vessel walls and degenerative changes [Figure 4].

Immunomodulatory activity

Effects of *Qurs Haiza* on cellular immune response

Treatment with *Qurs Haiza* at 620 mg/kg significantly increased the Hb level and lymphocyte count as compared to IM-Group II (negative control); however, no significant changes were observed in other cellular parameters [Table 2].

Effects *Qurs Haiza* on humoral immune response

Treatment with *Qurs Haiza* at 620 mg/kg significantly increased IgG and IgM as compared to IM-Group II (negative control) [Table 3].

Discussion

Drugs derived from natural sources, namely, plants, animals, and minerals, are the first remedies in all traditional systems of healing, including Unani, Ayurveda, Siddha, Homeopathy, and Chinese medicine.^[16] Access to herbal products is too easy in many developed and developing countries because of poor regulatory norms, and it is believed that they don't produce adverse effects.^[17] However, in the present scientific era, the safety profile and therapeutic effectiveness of herbal drugs are of greater apprehensions. Many scientific reports have evidenced that herbs can produce organ-level toxicities, including cardiotoxicity, renal toxicity, hepatic toxicity, genotoxicity, carcinogenicity, etc. Moreover, the

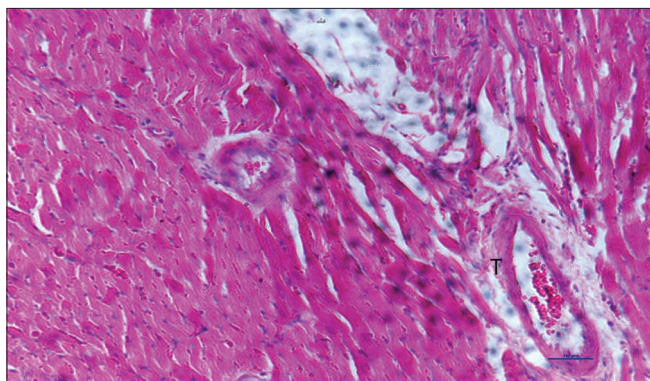


Figure 4: Heart of AT-Group III (disruption of muscle fibres with congestion and thickening of blood vessel wall [T]) H and E $\times 20$

adulteration with metals and spurious substances in herbal drugs are also responsible for producing several type of toxicities.^[16] Therefore, the safety profile of herbal drugs must be evaluated on scientific parameters. In the present acute toxicity study, *Qurs Haiza* did not produce any mortality even at the higher dose level, and its LD₅₀ was found to be higher than 5000 mg/kg for rats. Although mild toxic effects, such as tremors, abnormal gait, sluggish reflexes, circling, piloerection, Straub tail, writhing reflex, confusional state, and marked reduction in body weight on the 7th day in AT-Groups II and III were observed, which might be due to the higher dose levels and delayed excretion of the drug from the body. No marked changes were recorded in daily food intake and relative organ-body weight of liver, kidney, and heart in any groups. The histopathological findings, most importantly cellular infiltration and necrosis, showed the accumulation of *Qurs Haiza* in the liver, kidney, and heart. For a better conclusion, the toxicity findings of the present study have been correlated with the toxicities described in the classical Unani literature and scientific studies carried out on individual ingredients of *Qurs Haiza*. The Unani classical literatures describe that *Calotropis gigantea* (L.) Dryand., *Zingiber officinale* Roscoe, and *Piper nigrum* L., can produce weakness in visceral organs, gastric irritation, and kidney toxicity, respectively.^[18-20] The safety study conducted on an ethanolic extract of *Calotropis gigantea* at 2000 mg/kg did not evidence any death or toxic signs in experimental animals.^[21] The LD₅₀ of the methanolic extract of *Calotropis gigantea* (L.) Dryand. was calculated to be higher than 5000 mg/kg with mild hepatotoxic changes in rats.^[22] The LD₅₀ of *Zingiber officinale* Roscoe was observed to be >5000 mg/kg without producing significant toxic effects in hamster.^[23] Another study has reported hypotension, bradycardia, and precnrotic changes in the myocardium after giving a single dose of ginger at 2500 mg/kg in rats.^[24] Piperine, an active metabolite present in *Piper nigrum* L., has been reported to produce significant toxicities in the lower urinary tract, gastrointestinal tract, and adrenal glands.^[25] *Mentha arvensis* L. leaf extract at 3000 mg/kg has been found to be safe in an animal model.^[26] From the above-mentioned evidence, it is concluded that *Qurs Haiza* has produced mild toxicities at higher doses in rats due its ingredients, such as *Calotropis gigantea* (L.) Dryand., *Zingiber officinale* Roscoe, and *Piper nigrum* L.

Table 2: Effects of *Qurs Haiza* on cellular immune response in albino Wistar rats in immunomodulatory activity

Group	Hb	RBC	Platelet	TLC	Neutrophils	Lymphocytes	Monocytes	Eosinophils	Basophils
IM-Group I	12.61±1.05	6.6±0.63	874±114.9	8.53±1.62	28.36±2.65	66.55±2.73	2.35±0.44	2.3±0.315	0.63±0.475
IM-Group II	12.76±0.55	6.73±0.27	815.5±58.8	0.40±0.11	66.08±7.046	20.2±4.643	3.45±0.848	6.216±1.825	1.55±0.854
IM-Group III	12.38±0.97	6.31±0.63	659±81.64	0.41±0.11	65.56±3.691	28.96±3.74	2.233±0.549	1.883±0.6	1.35±0.944
IM-Group IV	13.33±0.20	6.55±0.22	582.5±86.25	0.38±0.13	56.65±11.60	31.27±12.76	2.9±0.72	3.16±0.95	0.966±0.36

Comparison between groups was made by One-way ANOVA followed by Bonferroni's multiple comparison test. Values are expressed as Mean±SEM (n=6). SEM: Standard error of mean, TLC: Total leukocyte count, Hb: Hemoglobin, RBC: Red blood cell count, IM: Immunomodulatory, ANOVA: Analysis of variance

Table 3: Effects of *Qurs Haiza* on humoral immune response in albino Wistar rats in immunomodulatory activity

Groups	Immunoglobulin		
	IgG	IgA	IgM
IM-Group I	403.83±51.708	31.96±0.261	42±5.466
IM-Group II	266±36.31	32.1±0.141	21.48±1.288
IM-Group III	250.16±21.10	32.38±0.177	22.96±1.549
IM-Group IV	312.83±31.43**	32.30±0.20	25.21±2.136**

** $P < 0.001$ (highly significant). Comparison between groups was made by One-way ANOVA followed by Bonferroni's multiple comparison test. Values are expressed as Mean±SEM ($n=6$).

SEM: Standard error of mean, IgG: Immunoglobulin G,

IM: Immunomodulatory, ANOVA: Analysis of variance,

IgA: Immunoglobulin A, IgM: Immunoglobulin M

At present, immunomodulators prepared with botanicals are chosen as an alternative therapy in place of immunomodulators prepared with synthetic materials, which produce severe adverse effects. The herbal-derived immunomodulators modulate the immune system through moderating the functions of various cells.^[27] The present study has reported that *Qurs Haiza* does not produce significant changes in any hematological parameters, except slight elevation on Hb and DLC levels at the dose level of 620 mg/kg. The immunoglobulin parameters, such as IgG and IgM, have been found to be significantly increased in IM-Group IV received *Qurs Haiza* at 620 mg/kg, in comparison to the IM-Group II (negative control). Immunoglobulin G and M are regarded as monomers and form primary and secondary immune responses, respectively, against pathogens and antigens. These immunoglobulins activate the classical pathway of the complementary system.^[28] Research studies conducted on botanical ingredients of *Qurs Haiza*, such as *Zingiber officinale* Roscoe, *Piper nigrum* L., *Mentha arvensis* L., and *Calotropis gigantea* (L.) Dryand., have shown significant immunomodulatory activities. An extract prepared with ginger, used orally (200 mg/kg) for 30 days, has shown a promising immunomodulatory potential in respect to increasing CD4 and CD8 T lymphocytes in an animal model of diabetes.^[29] The freeze-dried ethanol extract of *Zingiber officinale* Roscoe has shown the potential immunomodulatory, antioxidant, and anti-inflammatory activities against LPS-stimulated RAW264.7 murine macrophages.^[30] Both studies have suggested that [6]-gingerol and [6]-shogaol present in *Zingiber officinale* Roscoe are responsible for modulating the immune system.^[29,30] The extracts obtained from *Piper nigrum* L. and its major biologically active compound, piperine, has shown significant immunomodulatory effects in experimental models. A study has reported that piperine markedly decreased the production of polyclonal and antigen-specific T lymphocytes, CD25 expression, IL-2, IL-4, IL-17A, and interferon- γ .^[31] Piperine as an adjuvant with rifampicin has shown significant immunomodulatory effects through up-regulating Th1 immunity in an experimental

model of tuberculosis.^[32] An ethanolic extract prepared with *Piper longum* L. fruits (10 mg/kg), and its major alkaloid piperine (1.14 mg/kg) noticeably decreased the proliferation of Ehrlich ascites carcinoma and Dalton's lymphoma ascites cells and improved the TLC in Balb/c mice.^[33] A study revealed that 3% of *Mentha arvensis* L. extract promisingly increased the TLC, total protein, globulin, lysozyme activity, phagocytic indexes, IL-1, TNF, and MyD88 in *Clarias batrachus*.^[34] Several studies have confirmed the promising anti-angiogenesis, apoptosis induction, cytotoxic, and immunomodulatory activities of various secondary metabolites isolated from *Calotropis gigantea* (L.) Dryand.^[35] To date, serpentine stone, a mineral-origin drug, has not been investigated directly for its immunomodulatory activity, but a herbomineral Unani formulation, which contains serpentine stone, exhibited significant immune-potentiating effects by stimulating the Th1 immune system in mice.^[36] Taken together, it has been observed that the immunomodulatory activity of *Qurs Haiza* might be due to the synergistic effects of its ingredients. From the results of acute toxicity and immunomodulatory studies, it is concluded that *Qurs Haiza* can be safely used for the treatment of acute diarrheal diseases, including cholera. However, it is suggested that further toxicity studies on multiple dose levels may be carried out in the future.

Conclusions

From the inferences of an acute toxicity study in an animal model, it is concluded that *Qurs Haiza*, a herbomineral formulation, has a wide therapeutic window and can be safely used for various therapeutic purposes as indicated in the Unani literature. However, it is suggested that the mild toxicity findings of *Qurs Haiza* reported in the present study may be documented in the Unani literature for future reference. The significant modulation of the humoral immunity observed in the present study suggested that *Qurs Haiza* may be prescribed for the treatment of infectious diseases caused by viruses, bacteria, and fungi.

Limitations and future prospects

The present acute toxicity study was conducted using a single dose to identify the potential hazards and LD₅₀ value of *Qurs Haiza*. It is recommended that toxicity studies of the same formulation on multiple dose levels may be carried out in the future.

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Conflicts of interest

There are no conflicts of interest.

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Efficacy of *Ḍimād-i-Safūf-e-Waj* in Segmental Vitiligo

Abstract

Vitiligo (Baras) is a pigmentary disorder of the skin marked by circumscribed depigmented patches due to selective melanocyte loss, affecting 0.5%–2% of the population. The condition manifests as asymptomatic milky-white lesions that may be focal, segmental, or generalized. Conventional treatments, including corticosteroids, calcineurin inhibitors, phototherapy, and psoralen (PUVA), are often effective; however, they can induce adverse effects and may be refractory, particularly in cases of childhood or segmental *vitiligo* (SV). Herein we report a case of vitiligo which was treated with Unani drugs. A 10-year-old female presented with a 4-month history of depigmented patches on the right forehead, right angle of the mouth, jawline, and neck. Previous allopathic treatments provided no relief. She was prescribed topical application of *Waj* (*Acorus calamus* Linn.) mixed with water and applied once daily in the morning to lesions. After 1 month of topical *Waj* application, approximately 40%–50% repigmentation was achieved. A notable improvement was observed primarily along the peripheral margins of the patches. Previously, depigmented areas had exhibited scattered islands of pigments that were slightly lighter than the surrounding normal skin. Smaller patches on the neck and the angle of the mouth showed near-complete repigmentation, whereas larger facial patches demonstrated partial repigmentation. No adverse events were reported. This case suggests that Unani therapy may serve as a safe, effective, and culturally acceptable alternative for SV. Further controlled studies are warranted to validate the efficacy of this treatment.

Keywords: Case report, segmental vitiligo, Unani medicine, *Waj*

Introduction

Vitiligo is a depigmented skin disorder characterized by selective melanocyte depletion, resulting in loss of melanin within the affected areas. The hallmark feature is a completely amelanotic, nonscaly, chalky white macule with well-defined borders.^[1] Understanding the etiology of the disease has advanced considerably in recent years, and it is now categorically recognized as an autoimmune disorder. The contributing factors include metabolic and oxidative stress, defective cell adhesion, and genetic and environmental factors.^[2] *Vitiligo* is a relatively common condition with a global prevalence of 0.5% and 1%, respectively. It affects all age groups irrespective of sex, skin type, or ethnicity.^[3] The disease often follows a progressive and unpredictable course, leading to a significant decline in quality of life, self-esteem, and heightened social stigma.^[4] Patients with *vitiligo* are also at an increased risk of developing autoimmune comorbidities such as thyroid disorders, alopecia areata, and diabetes

mellitus.^[5] In 2011, a global consensus classified *vitiligo* into two main types: nonsegmental *vitiligo* (NSV) and segmental *vitiligo* (SV). The term *vitiligo* was adopted to refer to all NSV subtypes, including acrofacial, mucosal, generalized, universal, mixed, and rare variants. One of the most important decisions of this consensus is to distinguish SV as a separate entity owing to its prognostic implications.^[2] Treatment outcomes of SV are generally unsatisfactory. The most widely used therapeutic approaches include topical corticosteroids and calcineurin inhibitors, which target immune dysregulation, often in combination with narrowband ultraviolet B phototherapy. Additional topical agents, such as Vitamin D, pseudo-catalase, and depigmenting agents, are also commonly employed.^[6] In the Unani system of medicine, *Baras* (~*vitiligo*) refers to whitening of the skin and hair, either localized or generalized. This is attributed to excess phlegm in the blood and weakness of *Quwwat Mughayyira* (digestive faculty), leading to impaired *Quwwat Mushabbiha* (Faculty of Assimilation) under the influence of

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Mādda Ghalīza (~morbid matter) and excessive *Burūdat* (~coldness). Weak *Quwwat Dafia* (expulsive faculty) leads to the accumulation of *Madda Ghalīza* (~morbid matter), which disrupts nutrient assimilation and hinders skin color restoration.^[7] Management includes *Mundij wa Mushil* therapy (~concoction and evacuation of morbid matter), dietary regulation, hot-tempered medicines, and local applications such as *Muḥammir* (~dissipating drug) and *Akkāl* (~desiccant) *Ḍimād* (~ointment).^[8,9] Here, we present a case of SV that responded successfully to Unani treatment.

Case Report

A 10-year-old female patient was brought to the outpatient department with a 4-month history of depigmented skin patches on the right side of the forehead, right corner of the mouth, right jaw line, and right side of the neck. Parents reported that the lesion began as a small hypopigmented patch on the chin, followed by a gradual increase in size and number, along with complete loss of pigment from the patches [Figure 1]. There was no history of similar lesions elsewhere in the body, and no systemic symptoms were reported. The patient had no family history of *vitiligo* or atopic disorder. The patient reported emotional distress and occasional social embarrassment owing to the visibility of the lesion.

Clinical findings

Dermatological examination revealed multiple well-defined depigmented macules and patches of variable size on the right side of the forehead, jawline, chin, and side of the neck. There was no history of itching, scaling, or watery discharge. No lymphadenopathy or other systemic abnormalities were observed.

Diagnostic assessment

Wood lamp examination revealed bright white fluorescence. Dermoscopic evaluation of the lesion revealed a complete loss of pigment in the affected area. A definitive diagnosis of SV was established on the basis of clinical examination,

medical history, and wood lamp examination. Informed consent was obtained from the patient's parents prior to the commencement of treatment.

Therapeutic intervention

The patient was prescribed a powder of a single Unani drug, *Waj* (*Acorus calamus* Linn.) mixed with water for local application once daily for 30 days.^[10]

Follow-up and outcome

The patient was advised to apply *Ḍimād-i-Safūf-i-Waj* (ZSW) mixed with water over the lesions once daily after rubbing the affected area with a rough cotton cloth. Follow-up visits were scheduled on days 15th and 30th days of treatment to monitor the therapeutic response. At each follow-up, clinical examination and dermoscopic evaluation were performed to evaluate efficacy. After 15 days of treatment, the patch on the right corner of the mouth showed marked erythema, shrinkage of its margins, and the appearance of hyperpigmented dots within the lesion [Figure 2]. Approximately 40%–50% repigmentation was observed after 1 month of treatment. The most noticeable improvement occurred along the edges of depigmented patches. The previously white areas displayed scattered spots of new pigments that were somewhat lighter than the surrounding normal skin. Smaller lesions in the neck and corners of the mouth showed almost complete repigmentation [Figures 2 and 3]. The depigmented patch on the forehead did not show any repigmentation after 1 month of treatment. After 1 month of therapy, the patient demonstrated marked clinical improvement, with a significant reduction in the size of the depigmented patch and normalization of skin texture. She reported increased confidence in social interactions and an improved sense of psychological well-being, while family members also observed positive changes in mood and outlook. The treatment was well tolerated, with no adverse effects, and no further therapeutic measures were required during the follow-up period.



Figure 1: Before treatment



Figure 2: After 15 days of therapy



Figure 3: After 30 days of therapy

Discussion

The patient's symptoms improved significantly after 1 month of treatment. The lesions showed a remarkable improvement and were almost completely reduced [Figures 2 and 3]. The depigmented patch on the forehead did not show any repigmentation after 1 month of treatment. As noted in the Unani literature, *vitiligo* lesions over bony areas, such as the forehead, are often more resistant to therapy and may require longer treatment periods to show improvement.^[8] The efficacy of treatment can be attributed to the *Muhammir* (dissipating drug) and *Musakkin* (~calorific) action of *Waj*. These agents enhance the local circulation, eliminate excess phlegmatic matter, and restore cutaneous homeostasis.^[11] From a biomedical perspective, these Unani descriptions correlate with the oxidative stress theory of *vitiligo*, which proposes that elevated levels of reactive oxygen species, particularly hydrogen peroxide, induce melanocyte apoptosis and disrupt melanogenesis.^[1] The temperament of *Waj* is described as *Garm wa Khushk* (hot and dry) in the third degree.^[12] Avicenna (980–1037 AD) described it as *Garm wa Khushk* in the second degree.^[13] Drugs of *Garm wa Khushk* 2nd degree provide moderate thermogenic and desiccative effects, helping dissolve viscid phlegm and improve circulation, supporting cutaneous nourishment and restoration. Drugs of *Garm wa Khushk* 3rd degree (e.g., *Psoralea corylifolia* Linn.) possess stronger resolvents and stimulant actions. Their higher potency facilitates the aggressive removal of *Balgham-e-Ghaliz* (~morbid phlegmatic matter) and reactivation of melanogenesis, although they require careful use to avoid adverse reactions, such as local irritation or systemic heat.^[14] *Waj* has been applied in the form of *Dimād* (ointment) for *Baras wa Bahaq* (*vitiligo* and pityriasis).^[10] Recent pharmacological studies substantiated these applications. *A. calamus* L. has been used in Ayurveda, Unani, Siddha, and Chinese medicine and has shown neuroprotective, anti-inflammatory, and immunomodulatory effects. Its essential oils, rich in

α -asarone, β -asarone, and Z-isoelemicin, show potent antioxidant activity through DPPH radical-scavenging, reducing power, and Fe^{2+} chelation assays, with IC50 values ranging from 475.48 ± 0.08 to 11.72 ± 0.03 . The therapeutic use of thermogenic and antioxidant-rich drugs offers a convergent strategy: Eliminating morbid matter, restoring cutaneous temperament, and neutralizing oxidative stress to preserve melanocyte integrity.^[15]

Conclusion

This case report demonstrates the potential efficacy of Unani therapy in the treatment of SV. The ZSW application led to a significant improvement in white patches after 30 days of therapy. Given its promising results, Unani medicine may serve as a valuable complementary approach for treating *vitiligo*. Further research is required to substantiate these preliminary findings.

Patients perspective

According to the patients' parents, this condition affected their child's confidence, and she often avoided social situations. After 1 month of treatment, they observed a visible improvement in the patches and confidence. They were very satisfied with the progress and hoped for continued recovery.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given her consent for her images and other clinical information to be reported in the journal. The patient understands that name and initials will not be published and due efforts will be made to conceal identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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Therapeutic Efficacy of an Unani Traditional Regimen in Chronic Non-healing Ulcer

Abstract

Chronic nonhealing ulcers in the lower extremities caused by diabetes are responsible for developing noteworthy morbid conditions and poor quality of life, mainly due to loss of lower limbs. Therefore, a safe and effective alternative treatment approach may be searched for in order to minimize the complications. The Unani system of medicine offers effective and safe therapeutic regimens for the treatment of chronic nonhealing ulcers. A 52-year-old male patient with a clinical history of type 2 diabetes mellitus for the past 2 years and a chronic ulcer on the dorsal aspect of the left toe associated with pus formation, edema, and hyperpigmentation for the past 6 months was treated with the local application of a paste prepared with fresh herbs of *Heliotropium indicum* L. whole plant and *Datura metel* L. leaves on the ulcerated area and oral medications, including *Qurs Ziabetus Khas* and *Arq Kasni*, for 60 days. During the course of the treatment, the healing process was observed to be significant, and at the end of the treatment, the ulcer was observed to be healed completely with subsiding edema and the appearance of scar tissue. This case report underscores the potential of Unani medicine in effectively treating chronic nonhealing ulcers caused by diabetes. However, it is suggested that further comprehensive scientific exploration may be carried out on an adequate sample size.

Keywords: *Datura metel* L., *Heliotropium indicum* L., nonhealing ulcer, Unani medicine

Introduction

Chronic ulcers, also known as non-healing ulcers, are defined as spontaneous or traumatic lesions, typically in the lower extremities, that are unresponsive to initial therapy or persist despite appropriate care and do not heal within a specified period, associated with an underlying etiology that may be related to systemic disease or local disorders.^[1] Chronic nonhealing ulcer is a major health issue that affects an estimated 2–6 million individuals in the United States alone, with a global prevalence ranging from 1.9% to 13.1%.^[2] The incidence of chronic ulcers is expected to increase as the population ages and due to increased risk factors for atherosclerotic occlusion such as smoking, obesity, and diabetes.^[3] The prevalence of chronic wounds in the Indian community was reported as 4.5 per 1000 population, whereas that of acute wounds was nearly doubled at 10.5 per 1000 population.^[4] Lower extremity ulcers account for a significant proportion of chronic ulcers, particularly those caused by venous disease, diabetes,

or arterial disease.^[1] Foot or ankle ulcers precede more than 85% of lower limb amputations, and diabetes is one of the leading causes of nontraumatic amputations worldwide.^[5] In the Unani system of medicine, an ulcer is referred to as *Qarḥa*, which is defined as the discontinuation of surface tissues containing pus. Based on the course and prognosis, it is classified into three types: (i) *Qurūḥ-i-Baseet* (simple ulcer) is considered to be noninfected, and the healing process is fast; (ii) *Qurūḥ-i-Murakkab* (compound ulcer) is associated with pain, suppuration, and blackening of surrounding tissues; (iii) *Qarḥa 'Asir al-Indimāl* (non-healing ulcer) does not show any tendency toward healing and is associated with more damage and destruction of tissues.^[6]

Individuals with diabetic foot ulcers are prone to infection, and the healing process is hampered by diabetic neuropathy, which results in persistent nonhealing ulcers. Most chronic lower extremity ulcers are caused by venous disease, as venous hypertension damages vessel walls and eventually leads to skin breakdown.^[1] These types of ulcers have a significant impact on the health and

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quality of life of patients and their families, causing pain, loss of function and mobility, depression, embarrassment and social isolation, prolonged hospital stays, and chronic morbidity and mortality, and they also impose a substantial financial burden not only on the individual but also on the healthcare system and the society as a whole.^[7,8]

Conventional treatment for non-healing ulcers comprises wound cleansing, necrotic tissue debridement, preventing infection, mechanical off-loading, blood glucose management, and local ulcer care with dressing application.^[2] However, certain risk factors commonly affect and contribute to poor wound healing, such as the presence of debris or necrotic tissues, infection in the ulcer, tissue hypoxia, repeated trauma, diabetes mellitus, immunodeficiency, malnutrition, and use of corticosteroids.^[9] Advanced wound care therapies such as skin grafting, hyperbaric oxygen therapy, topical application of platelet-derived growth factors, and vacuum-assisted wound closure have limitations in their applicability and uniformity in the treatment.^[10,11] Many chronic ulcers do not heal or linger for years after treatment. In addition, conventional therapy is costly, uncomfortable, and less effective; it also frequently results in huge numbers of handicapped people due to the amputation of legs, necessitating natural wound care therapies for the treatment of nonhealing ulcers.^[9]

The Unani system of medicine is rich in effective treatments and medications for nonhealing ulcers. It is less expensive, easily available, has better cultural and societal acceptance, is more compatible with the human physiological system, and has significantly fewer adverse effects. Such types of ulcers can be treated efficiently with the drugs having *mujaffif-i-qurūh* (desiccant), *jālī* (detergent), *mundammil-i-qurūh* (cicatrizant), *munbit-i-laḥm* (granulation tissue grower), *muḥallil* (resolvent), *man-i-alam* (analgesic), *daf-i-taffun* (antiseptic), and *hābis al-dam* (hemostyptic) properties.^[12] *Heliotropium indicum* L. and *Datura metel* L. are highly valued drugs in Unani and other traditional systems of medicine for treating wounds and ulcers among several other conditions. These plants have been reported to possess antioxidant, wound healing, antibacterial, hypoglycemic, anti-inflammatory, anti-ulcer, analgesic, and antithrombotic pharmacological activities.^[13,14]

Case Report

Brief history

A 52-year-old male patient visited the outpatient department of the Regional Research Institute of Unani Medicine (RRIUM), Chennai, Tamil Nadu, India (National Accreditation Board for Hospitals and Healthcare Providers and National Accreditation Board for Testing and Calibration Laboratories accredited), on February 20, 2025, presenting a history of diabetes for the past 2 years and a nonhealing ulcer on the dorsal aspect of the left toe associated with pus formation, edema, and

hyperpigmentation in surrounding tissues for the past 6 months. The patient had no history of smoking or any other systemic diseases except type 2 diabetes mellitus. He had no family history of diabetes and nonhealing ulcers. Before visiting RRIUM, Chennai, he approached modern conventional treatment, which comprised local wound care for the same. After receiving modern conventional treatment, including removal of debridement, antiseptic dressing, antibiotics, and anti-inflammatory drugs, the ulcer showed minimal therapeutic response.

Physical examination

The ulcer was found to be deep, situated around 2.5 cm in the deeper tissues of the greater toe of the left foot, and surrounded by debridement and necrotic tissues. The length and width of the ulcer were approximately 5 cm and 4 cm, respectively. The margin of the ulcer was found to be irregular, and the deeper surface was contaminated with debridement and slough tissues. It was observed that the edema in the whole left foot is due to the continuous walking of the patient [Figure 1]. The sensation in the affected toe and its surrounding areas was found to be normal. The general condition and vitals of the patient were found to be stable.

Investigations

The blood sugar level, glycated hemoglobin (HbA1c), renal function tests, and venous Doppler study were done before starting the treatment of the nonhealing ulcer at RRIUM, Chennai. The blood sugar level was also checked at regular intervals. On the 1st day of the treatment, the fasting blood sugar (FBS) and postprandial blood sugar (PPBS) levels and HbA1c were estimated to be 136 mg/dL, 211 mg/dL, and 10.5, respectively.

Diagnosis

The diagnosis was made based on the Clinical-Etiology-Anatomy-Pathophysiology classification system, which includes clinical presentation, etiology (cause), anatomy (location), and pathophysiology (how the disorder works),^[15] and the case was diagnosed as nonhealing ulcer caused by type 2 diabetes mellitus. The FBS, PPBS, and HbA1c were found to be raised, but the renal function was found to be



Figure 1: (a) Ulcer before the treatment, (b) Edema and hyperpigmentation on the left greater toe and left foot

normal. The venous Doppler study of the left lower limb exhibited diffuse subcutaneous edema in the left lower leg and foot region and left inguinal lymphadenopathy but no evidence of deep venous thrombosis. The ethical principles of the Declaration of Helsinki and Care Case Report guidelines were strictly followed in publishing this case report.^[16]

Unani regimen

The treatment was started on March 12, 2025, which includes the local application of the paste prepared with the fresh herbs of the whole plant of *H. indicum* L. and leaves of *D. metel* L. [Figure 2a and b] on the ulcerated area and oral medications. The paste of the above-mentioned herbs was freshly prepared by crushing them into an electric mixer daily just before its application [Figure 2c and d], followed by the wound being cleaned using Savlon antiseptic liquid and the paste being applied on the wound [Figure 3a] and packed with a bandage daily for 60 days. Simultaneously, oral medications, including antidiabetic and anti-inflammatory medicines, were given. Initially, the local

application of the paste prepared with *H. indicum* L. and *D. metel* L. was applied in the inpatient department for 5 days. The patient was then educated on the preparation and application of the paste, and he was advised to do the same at home for 55 days. The oral medications, including *Qurs Ziabetus Khas* 2 g and *Arq Kasni* 100 ml, were given daily for 60 days. The patient visited the outpatient department of RRIUM, Chennai, every 10 days till completion of the treatment. At every follow-up, the condition of the ulcer and the vitals of the patient were examined.

Ethical consideration

The obtained informed consent has mentioned that the identity of the patient will not be disclosed and the information related to the treatment outcome will be published in a journal to disseminate the medical information.

Outcome

The process of healing, including inflammatory reactions, vascular formation, and presence of granulation tissues, was observed after 15 days [Figure 3b], and the complete



Figure 2: (a) *Heliotropium indicum* L., (b) *Datura metel* L., (c) Both herbs for preparing paste, (d) Prepared paste

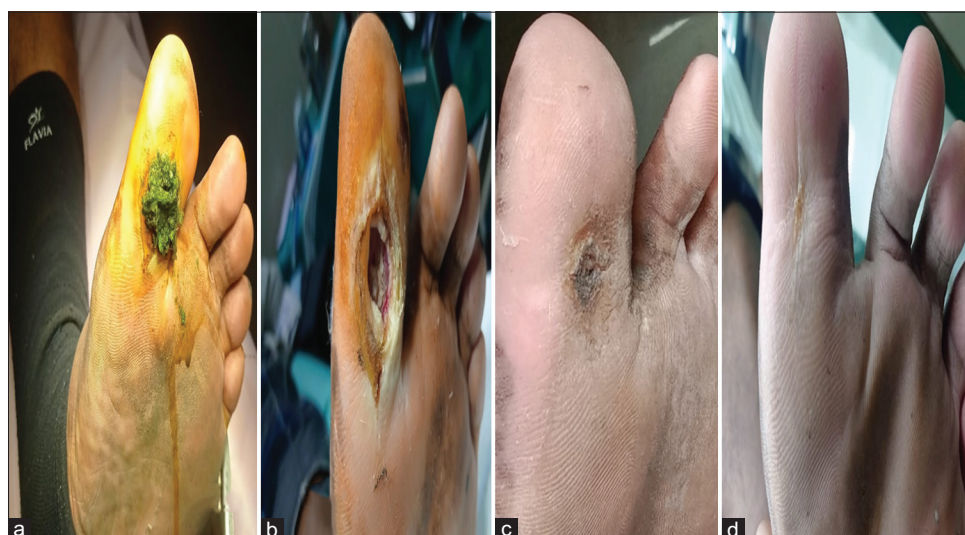


Figure 3: (a) Ulcer packed with herbal paste, (b) Ulcer after 15 days of treatment, (c) Ulcer after 45 days of treatment, (d) Ulcer after 60 days of treatment

healing process except the formation of complete scar tissues was observed after 45 days of the treatment [Figure 3c]. However, the complete scar tissues were developed after 60 days of the treatment [Figure 3d]. The edema and hyperpigmentation over the left great toe and left foot had also subsided completely. No clinical adverse effects due to the local application of the paste and oral medications used in this case were observed during the entire course of the treatment. The blood sugar level was found to be controlled during the entire course of the treatment. The random blood sugar level was found to be 130 mg/dL when the ulcer got completely healed.

Discussion

The present case report potentiates the effectiveness of the Unani regimen used in the treatment of a non-healing ulcer caused by type 2 diabetes mellitus. The highly significant outcome in reducing signs and symptoms and improving the entire healing process of the ulcer is attributed to the multifaceted mechanistic role of the herbal paste and oral medications used in the present case. Unani literature advocates that the paste prepared with the fresh plants of *H. indicum* L. and *D. metel* L. is beneficial in treating boils, wounds, and ulcers.^[14,17,18] The folklore claims by tribes of Kanchipuram district of Tamil Nadu state in India for the use of *H. indicum* in the treatment of wounds and skin diseases are also evident.^[19,20] An experimental study revealed that the aqueous and methanol extracts of *H. indicum* L. leaves have produced promising healing effects as compared to nitrofurazone in excision and incision wound models induced in Wistar rats.^[21] The wound healing potential of ethanol extracts of *H. indicum* L., *Plumbago zeylanica* L., and *Acalypha indica* L. was investigated against the excision and incision wound models in Wistar rats. The topical application of 10% w/v ethanol extract of *H. indicum* L. exhibited a highly significant wound healing outcome as compared to *P. zeylanica* L. and *A. indica* L.^[22] Two important alkaloids, namely pestalamide B and glycinamide, *N*-(1-oxooctadecyl) glyceryl-lalanyl-glycyl-L-histidyl present in *H. indicum*, have been reported to possess wound healing activity. Several studies have reported that the methanol, petroleum ether, chloroform, and aqueous extracts of different parts of *H. indicum* possess significant anti-inflammatory activity as compared to reference drugs against various models in animals. Studies have also reported significant antimicrobial activity of different extracts of *H. indicum* against many microorganisms, including *Staphylococcus aureus*, *Bacillus subtilis*, *Pseudomonas aeruginosa*, *Proteus vulgaris*, *Bacillus pumilus*, *Micrococcus glutamicus*, *Escherichia coli*, *Serratia marcescens*, *Candida albicans*, *Aspergillus niger*, *Aspergillus wentii*, *Saccharomyces cerevisiae*, and *Rhizopus oryzae*. The ethanolic and methanolic extracts of different parts of *H. indicum* L., such as leaf, stem, and roots, have been reported to have promising antioxidant activity attributed to the higher concentration

of phenolic and flavonoid contents.^[19] The wound healing activity of the green extracts of *D. metel* L. obtained from supercritical carbon dioxide extraction method is attributed to the multifaceted mechanistic principles, including anti-inflammatory and antioxidant activity, improved cellular proliferation, and decreased MMP-2 enzyme activity that is responsible for the breakdown of collagen due to the presence of loliolide, schisanhenol, and farnesyl acetone bioactive compounds.^[23] The methanolic extract of *D. metel* L. leaves depicted marked anti-inflammatory, antimicrobial, antioxidant, antidiabetic, and wound healing properties against different experimental models due to the presence of isolated bioactive molecules, such as hexadecenoic acid, hentriacontane, and neophytadiene.^[24] An ointment prepared with the ethanol extract of *D. metel* L. was investigated against the excision wound model contaminated with *E. coli* in Wistar rats. Following daily application of the ointment on the wound area for 16 days, it was observed that the significant wound healing, antibacterial, and antioxidant effects of the ointment are attributed to many biologically active compounds, including flavonoids, alkaloids, tannins, and saponins.^[25] *Qurs Ziabetus Khas*, a potential Unani pharmacopeial preparation, is often used to reduce the high blood sugar level in patients with diabetes mellitus.^[26] A clinical study validated the claims of Unani medicine with scientific evidence in significantly reducing the high blood sugar level in patients with type 2 diabetes mellitus.^[27] Moreover, a preclinical study conducted on an alloxan-induced diabetic model in rabbits has been reported to possess highly significant hypoglycemic control of *Qurs Ziabetus Khas* as compared to glibenclamide.^[28] The important ingredients of *Qurs Ziabetus Khas*, including *Tinospora cordifolia* (Thunb.) (polyphenols, alkaloids, and terpenes) Miers, *Syzygium cumini* (L.) Skeels (gallic acid and polyphenolic compounds), and *Gymnema sylvestre* R. Br. (tannin, quinones, flavonoids, phenols, and saponins), have been reported to possess promising hypoglycemic activity, as evident in many scientific studies.^[29] *Arq Kasni* (distillate of *Cichorium intybus* L.) is prescribed to resolve inflammatory conditions and other swellings.^[26] The flavonoids, glycosides, sterols, and polyphenols present in *C. intybus* have been reported to have significant anti-inflammatory activity by inhibiting the synthesis of various cytokines such as prostaglandins, tumor necrosis factor- α , interleukin (IL)-6, IL-1, and nitric oxide.^[30]

The hypothesized mechanism of action of the prescribed Unani regimen in the present case suggests the role of anti-inflammatory, antimicrobial, and antioxidant activities; improved blood circulation and cellular proliferation; vasodilatation; inhibiting platelet aggregation; growth of granulation tissues; epithelialization; and subsiding inflammation, edema, and pain.

The limitation of this case report is that the present outcome is based on the clinician's observational findings

after using an Unani regimen in a single patient with a nonhealing ulcer caused by type 2 diabetes mellitus. The observational findings in improving the clinical features and healing of the ulcer were recorded before, during, and after treatment, suggesting the therapeutic role of the paste prepared with *H. indicum* L. and *D. metel* L. However, this clinical outcome may be validated in the future through a well-designed and comprehensive clinical trial on an adequate sample size.

The patient was found to be mentally disturbed and was thinking that his great toe of the left foot may be amputated in the future because of a nonhealing ulcer and diabetes. However, when the ulcer got completely healed after receiving the Unani treatment for 2 months, his mental and emotional conditions were observed to be normal. Now, he is happily performing his personal and professional responsibilities.

Conclusion

The herbal paste prepared with *H. indicum* L. and *D. metel* L. resulted in complete healing of the deep-seated ulcer and resolved its associated clinical features, including pain, swelling, edema, and hyperpigmentation in a patient with comorbidities such as type 2 diabetes mellitus and disability in mobility. The present case report proposes a hypothesis for further exploration of the herbal paste prepared with fresh plants of *H. indicum* L. and *D. metel* L. in the treatment of nonhealing ulcers. It is also suggested that this traditional dosage form may be converted either into ointment or cream containing extracts of both medicinal plants and further extensive research studies may be carried out in animal and human models by employing a standardized wound scoring system and comprehensive parameters in order to generate wider efficacy and safety data.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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Water-soluble ash	11.2%
Insoluble ash	9.8%
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Total oil	4%

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 Kirmani, Ayman; Nengroo, Rasikh Javaid; Aslam, M.; More
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